Foam surfaces for preventing pressure ulcers

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Abstract

Background

Pressure ulcers (also known as pressure injuries) are localised injuries to the skin or underlying soft tissue, or both, caused by unrelieved pressure, shear or friction. Foam surfaces (beds, mattresses or overlays) are widely used with the aim of preventing pressure ulcers.

Objectives

To assess the effects of foam beds, mattresses or overlays compared with any support surface on the incidence of pressure ulcers in any population in any setting.

Search methods

In November 2019, we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations); Ovid Embase and EBSCO CINAHL Plus. We also searched clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

We included randomised controlled trials that allocated participants of any age to foam beds, mattresses or overlays. Comparators were any beds, mattresses or overlays.

Data collection and analysis

At least two review authors independently assessed studies using predetermined inclusion criteria. We carried out data extraction, 'Risk of bias' assessment using the Cochrane 'Risk of bias' tool, and the certainty of the evidence assessment according to Grading of Recommendations, Assessment, Development and Evaluations methodology. If a foam surface was compared with surfaces that were not clearly specified, then the included study was recorded and described but not considered further in any data analyses.

Main results

We included 29 studies (9566 participants) in the review. Most studies were small (median study sample size: 101 participants). The average age of participants ranged from 47.0 to 85.3 years (median: 76.0 years). Participants were mainly from acute care settings. We analysed data for seven comparisons in the review: foam surfaces compared with: (1) alternating pressure air surfaces, (2) reactive air surfaces, (3) reactive fibre surfaces, (4) reactive gel surfaces, (5) reactive foam and gel surfaces, (6) reactive water surfaces, and (7) another type of foam surface. Of the

29 included studies, 17 (58.6%) presented findings which were considered at high overall risk of bias.

Primary outcome: pressure ulcer incidence

Low-certainty evidence suggests that foam surfaces may increase the risk of developing new pressure ulcers compared with (1) alternating pressure (active) air surfaces (risk ratio (RR) 1.59, 95% confidence interval (CI) 0.86 to 2.95; I^2 = 63%; 4 studies, 2247 participants), and (2) reactive air surfaces (RR 2.40, 95% CI 1.04 to 5.54; I^2 = 25%; 4 studies, 229 participants).

We are uncertain regarding the difference in pressure ulcer incidence in people treated with foam surfaces and the following surfaces: (1) reactive fibre surfaces (1 study, 68 participants); (2) reactive gel surfaces (1 study, 135 participants); (3) reactive gel and foam surfaces (1 study, 91 participants); and (4) another type of foam surface (6 studies, 733 participants). These had very low-certainty evidence.

Included studies have data on time to pressure ulcer development for two comparisons. When time to ulcer development is considered using hazard ratios, the difference in the risk of having new pressure ulcers, over 90 days' follow-up, between foam surfaces and alternating pressure air surfaces is uncertain (2 studies, 2105 participants; very low-certainty evidence). Two further studies comparing different types of foam surfaces also reported time-to-event data, suggesting that viscoelastic foam surfaces with a density of 40 to 60 kg/m^3 may decrease the risk of having new pressure ulcers over 11.5 days' follow-up compared with foam surfaces with a density of 33 kg/m^3 (1 study, 62 participants); and solid foam surfaces may decrease the risk of having new pressure ulcers over one month's follow-up compared with convoluted foam surfaces (1 study, 84 participants). Both had low-certainty evidence.

There was no analysable data for the comparison of foam surfaces with reactive water surfaces (one study with 117 participants).

Secondary outcomes

Support-surface-associated patient comfort: the review contains data for three comparisons for this outcome. It is uncertain if there is a difference in patient comfort measure between foam surfaces and alternating pressure air surfaces (1 study, 76 participants; very low-certainty evidence); foam surfaces and reactive air surfaces (1 study, 72 participants; very low-certainty evidence); and different types of foam surfaces (4 studies, 669 participants; very low-certainty evidence).

All reported adverse events: the review contains data for two comparisons for this outcome. We are uncertain about differences in adverse effects between foam surfaces and alternating pressure (active) air surfaces (3 studies, 2181 participants; very low-certainty evidence), and between foam surfaces and reactive air surfaces (1 study, 72 participants; very low-certainty evidence).

Health-related quality of life: only one study reported data on this outcome. It is uncertain if there is a difference (low-certainty evidence) between foam surfaces and alternating pressure (active) air surfaces in health-related quality of life measured with two different questionnaires, the EQ-5D-5L (267 participants) and the PU-QoL-UI (233 participants).

Cost-effectiveness: one study reported trial-based cost-effectiveness evaluations. Alternating pressure (active) air surfaces are probably more cost-effective than foam surfaces in preventing pressure ulcer incidence (2029 participants; moderate-

certainty evidence).

Authors' conclusions

Current evidence suggests uncertainty about the differences in pressure ulcer incidence, patient comfort, adverse events and health-related quality of life between using foam surfaces and other surfaces (reactive fibre surfaces, reactive gel surfaces, reactive foam and gel surfaces, or reactive water surfaces). Foam surfaces may increase pressure ulcer incidence compared with alternating pressure (active) air surfaces and reactive air surfaces. Alternating pressure (active) air surfaces are probably more cost-effective than foam surfaces in preventing new pressure ulcers.

Future research in this area should consider evaluation of the most important support surfaces from the perspective of decision-makers. Time-to-event outcomes, careful assessment of adverse events and trial-level cost-effectiveness evaluation should be considered in future studies. Trials should be designed to minimise the risk of detection bias; for example, by using digital photography and by blinding adjudicators of the photographs to group allocation. Further review using network meta-analysis will add to the findings reported here.

Plain language summary

Do mattresses and mattress toppers made of foam prevent pressure ulcers?

Key messages

Mattresses and mattress toppers made of foam:

- may increase the risk of developing pressure ulcers when compared with air-filled surfaces;

- are probably less cost-effective than air-filled surfaces that regularly redistribute pressure under the body.

It is unclear if foam has an effect on pressure ulcers compared with surfaces made of fibre, gel or water cells.

Future studies should focus on options and effects that are important to decision-makers, such as:

- gel surfaces that apply constant skin pressure, compared with foam surfaces; and

- whether and when pressure ulcers develop, unwanted effects and costs.

What are pressure ulcers?

Pressure ulcers are also known as pressure sores or bed sores. They are wounds to the skin and underlying tissue caused by prolonged pressure or rubbing. They often occur on bony parts of the body, such as heels, elbows, hips and the bottom of the spine. People who have mobility problems or who lie in bed for long periods are at risk of developing pressure ulcers.

What did we want to find out?

There are beds, mattresses and mattress toppers specifically designed for people at risk of pressure ulcers. These can be made of a range of materials (such as foam, fibre, air cells or water bags) and are divided into two groups:

- reactive (static) surfaces that apply a constant pressure to the skin, unless a person moves or is repositioned; and

- active (alternating pressure) surfaces that regularly redistribute the pressure under the body.

We wanted to find out if mattresses and mattress toppers made of foam (a reactive surface):

- prevent pressure ulcers;

- are comfortable and improve people's quality of life;

- have health benefits that outweigh their costs (cost-effectiveness); and

- have any unwanted effects.

What did we do?

We searched the medical literature for studies that evaluated the effects of mattresses and mattress toppers made of foam. We compared and summarised their results, and rated our confidence in the evidence, based on factors such as study methods and sizes.

What did we find?

We found 29 studies (9566 people, average age: 76 years) that lasted between five days and one year (average: 15 days). The studies compared foam with active and reactive surfaces made of gel, air cells, water bags and other foam types.

Pressure ulcer prevention

The evidence suggests that:

- foam surfaces may increase the risk of developing pressure ulcers when compared with active or reactive air-filled surfaces (8 studies);

- denser memory foam (foam that adapts to a person's body shape) may be better than lighter memory foam for preventing pressure ulcers if the data on the time it takes to develop a new ulcer is looked at (1 study, duration: 11.5 days);

- flat foam surfaces may be better than ridged foam surfaces for preventing pressure ulcers if the data on the time it takes to develop a new ulcer is looked at (1 study, duration: 1 month).

It is unclear if foam has an effect on pressure ulcers compared to water or gel surfaces.

Other effects

Evidence from one study suggests that foam is probably less cost-effective than active, air-filled surfaces.

We did not find sufficiently robust and clear evidence to determine how foam affects comfort, quality of life and unwanted effects.

What limited our confidence in the evidence?

Most studies were small (101 people on average) and more than half (17 studies) used methods likely to introduce errors in their results.

How up-to-date is this review?

The evidence in this Cochrane Review is current to November 2019.

Summary of findings

Summary of findings 1

Foam surfaces compared with alternating pressure (active) air surfaces for pressure ulcer prevention

Foam surfaces compared with alternating pressure (active) air surfaces for pressure ulcer prevention

Patient or population: pressure ulcer prevention
Setting: any care setting
Intervention: foam surfaces
Comparison: alternating pressure (active) air surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with alternating pressure (active) air surfaces	Risk with foam surfaces				
Proportion of participants developing a new pressure ulcer Follow-up: median 90 days	Study population 74 per 1,000	117 per 1,000 (63 to 218)	RR 1.59 (0.86 to 2.95)	2247 (4 RCTs)	⊕⊕⊖⊖ Low[a,b]	Foam surfaces may increase the proportion of participants developing a new pressure ulcer compared with alternating pressure (active) air surfaces.
Time to pressure ulcer development Follow-up: median 60 days	Study population 68 per 1,000	159 per 1,000 (42 to 501)	HR (2.46 (0.61 to 9.88	2105 (2 RCTs)	⊕⊖⊖⊖ Very low[b,c,d]	It is uncertain whether there is a difference in the risk of developing a new pressure ulcer, over 90 days' follow-up, between foam surfaces and alternating pressure (active) air surfaces.
Support surface associated patient comfort Follow-up: 30 days	Sauvage 2017 presented data for the questionnaire's subscales as numbers and percentages of responders with the specific subscales, and reported no significant difference in the overall satisfaction between study groups (P = 0.21).		-	76 (1 RCT)	⊕⊖⊖⊖ Very low[e,f]	It is uncertain whether there is any difference in support surface associated patient comfort between alternating pressure (active) air

						surfaces and foam surfaces.
All reported adverse events Follow-up: range 30 days to 6 months	Nixon 2019 and Sauvage 2017 reported similar rates of adverse events between their study arms. Rosenthal 2003 reported 1 death but did not specify which study group the death was associated with.		-	2181 (3 RCTs)	⊕⊖⊖⊖ Very low[g,h]	It is uncertain whether there is any difference in all reported adverse events between alternating pressure (active) air surfaces and foam surfaces.
Health-related quality of life (90-day EQ-5D-5L, expressed as utility values ranging from −1 to 1 with 1 representing perfect health, 0 representing death, and −1 representing worse than death) Follow-up: 90 days	The mean health-related quality of life (90-day EQ-5D-5L) was 0.52.	MD 0 (0.05 lower to 0.05 higher)	-	267 (1 RCT)	⊕⊕⊖⊖ Low[i]	It is uncertain if there is a difference in health-related quality of life measured using EQ-5D-5L at 90-day follow-up between foam surfaces and alternating pressure (active) air surfaces.
Health-related quality of life (90-day PU-QoL-UI, expressed as utility values ranging from −1 to 1 with 1 representing perfect health, 0 representing death, and −1 representing worse than death) Follow-up: 90 days	The mean health-related quality of life (90-day PU-QoL-UI) was 0.60.	MD 0 (0.03 lower to 0.03 higher)	-	233 (1 RCT)	⊕⊕⊖⊖ Low[i]	It is uncertain if there is a difference in health-related quality of life measured using PU-QoL-UI at 90-day follow-up between foam surfaces and alternating pressure (active) air surfaces.
Cost-effectiveness Follow-up: 90 days	Incremental cost-effectiveness ratio (ICER) = GBP –101,699 and net-monetary benefit (NMB) = GBP –2114 in the probabilistic analysis, meaning alternating pressure (active) air surfaces have lower costs and higher quality-adjusted life-years (QALY) values. Alternating pressure (active) air surfaces had a 99% probability of being cost-effective at a threshold of GBP		-	1 RCT	⊕⊕⊕⊖ Moderate[j]	Alternating pressure (active) air surfaces probably dominate foam surfaces, meaning they are the cost-effective option.

	20,000 and alternating pressure (active) air surfaces dominated reactive foam surfaces.				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio; **HR**: hazard ratio; **MD**: mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded once for risk of bias (2 studies with about 50% of weight in the analysis had either 1 domain other than performance bias at high risk of bias or all domains at unclear risk of bias; 2 studies with about 50% of weight in the analysis had domains other than performance bias at low or unclear risk of bias).

[b]Downgraded once for moderate imprecision as, despite the fact that the optimal information size (OIS) was met, the wide confidence interval crossed RR = 1.25.

[c]Downgraded once for high risk of bias in one study with 40% of analysis weight but low risk of bias in domains other than performance bias in another study.

[d]Downgraded twice for substantial inconsistency (I^2 = 86%; Chi^2 test P = 0.009; point estimates and confidence intervals largely vary between studies).

[e]Downgraded twice for high risk of detection bias.

[f]Downgraded once for imprecision due to small sample size.

[g]Downgraded once for unclear risk of bias in two studies with about half weight.

[h]Downgraded twice for substantial inconsistency.

[i]Downgraded twice for substantial imprecision due to small sample size.

[j]Downgraded once for imprecision for the EQ-5D-5L outcome of the relevant study.

Summary of findings 2

Foam surfaces compared with reactive air surfaces for pressure ulcer prevention

Foam surfaces compared to reactive air surfaces for pressure ulcer prevention

Patient or population: pressure ulcer prevention
Setting: acute care setting, intensive care unit, and nursing home
Intervention: foam surfaces
Comparison: reactive air surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with reactive air surfaces	Risk with foam surfaces				
Proportion of participants developing a new pressure ulcer Follow-up: range 13 days to 6 months	Study population		RR 2.40 (1.04 to 5.54)	229 (4 RCTs)	⊕⊕⊖⊖ Low[a,b]	Foam surfaces may increase the proportion of participants developing a new pressure ulcer compared with reactive air surfaces.
	106 per 1,000	255 per 1,000 (110 to 588)				

Time to pressure ulcer development	Included studies did not report this outcome.				
Support surface associated patient comfort Follow-up: 13 days	More people using reactive air surfaces had comfort increased than using foam surfaces on top of an alternating pressure (active) air surface; less had comfort decreased (P = 0.04).	-	72 (1 RCT)	⊕⊖⊖⊖ Very low[c,d]	It is uncertain if there is a difference in patient comfort responses between reactive air surfaces and foam surfaces on top of an alternating pressure (active) air surface.
All reported adverse events Follow-up: 13 days	There appeared to be similar rates of patients having adverse events between those using foam surfaces and those using reactive air surfaces.	-	72 (1 RCT)	⊕⊖⊖⊖ Very low[c,d]	It is uncertain if there is a difference in adverse events between foam surfaces and reactive air surfaces.
Health-related quality of life	Included studies did not report this outcome.				
Cost-effectiveness	Included studies did not report this outcome.				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

__CI:__ confidence interval; __RR:__ risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded once for risk of bias (1 study contributing 8% weight in the meta-analysis had domains other than performance bias at high risk of bias and all the remaining studies had domains other than performance bias at low or unclear risk of bias).

[b]Downgraded once for imprecision as, despite the fact that the optimal information size is met, the 95% CI crossed RR = 1.25.

[c]Downgraded once for unclear risk of bias.

[d]Downgraded twice for imprecision due to the small sample size.

Summary of findings 3

Foam surfaces compared with reactive fibre surfaces for pressure ulcer prevention

Foam surfaces compared to reactive fibre surfaces for pressure ulcer prevention
Patient or population: pressure ulcer prevention **Setting:** acute care setting **Intervention:** foam surfaces **Comparison:** reactive fibre surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with reactive fibre surfaces	Risk with foam surfaces				
Proportion of participants developing a new pressure ulcer Follow-up: unspecified	Study population		RR 1.17 (0.64 to 2.14)	68 (1 RCT)	⨁⊖⊖⊖ Very low[a,b]	It is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between foam surfaces and reactive fibre surfaces.
	353 per 1,000	413 per 1,000 (226 to 755)				
Time to pressure ulcer development	The included study did not report this outcome.					
Support surface associated patient comfort	The included study did not report this outcome.					
All reported adverse events	The included study did not report this outcome.					
Health-related quality of life	The included study did not report this outcome.					
Cost-effectiveness	The included study did not report this outcome.					

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded twice for unclear risk of bias in all domains.

[b]Downgraded twice for imprecision as the OIS was not met and the wide confidence interval crossed RRs = 0.75 and 1.25.

Summary of findings 4

Foam surfaces compared with reactive gel surfaces for pressure ulcer prevention

Foam surfaces compared to reactive gel surfaces for pressure ulcer prevention
Patient or population: pressure ulcer prevention **Setting:** operating room **Intervention:** foam surfaces **Comparison:** reactive gel surfaces

Outcomes	Impact	№ of participants (studies)	Certainty of the evidence (GRADE)
Proportion of participants developing a new pressure ulcer Follow-up: unspecified	Hoshowsky 1994, involving a totality of 135 individuals (270 halves of bodies), indicated no pressure ulcers developed in either group.	270 (1 RCT)	⨁⊖⊖⊖ Very low[a,b]
Time to pressure ulcer development	The included study did not report this outcome.		
Support surface associated patient comfort	The included study did not report this outcome.		
All reported adverse events	The included study did not report this outcome.		
Health-related quality of life	The included study did not report this outcome.		
Cost-effectiveness	The included study did not report this outcome.		

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded twice for high risk of bias in domains other than performance bias.
[b]Downgraded twice for imprecision due to the small sample size and the low event rate.

Summary of findings 5

Foam surfaces compared with reactive foam and gel surfaces for pressure ulcer prevention

Foam surfaces compared to reactive foam and gel surfaces for pressure ulcer prevention

Patient or population: pressure ulcer prevention
Setting: operating room
Intervention: foam surfaces
Comparison: reactive foam and gel surfaces

Outcomes	Impact	№ of participants (studies)	Certainty of the evidence (GRADE)
Proportion of participants developing a new pressure ulcer Follow-up: unspecified	Hoshowsky 1994 compared foam surfaces and reactive foam and gel surfaces in 91 participants (with 182 halves of bodies) using a split body design. The study authors found that no pressure ulcers developed in either group.	182 (1 RCT)	⨁⊖⊖⊖ Very low[a,b]
Time to pressure ulcer development	The included study did not report this outcome.		
Support surface associated patient comfort	The included study did not report this outcome.		
All reported adverse events	The included study did not report this outcome.		
Health-related quality of life	The included study did not report this outcome.		

Cost-effectiveness	The included study did not report this outcome.

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded twice for high risk of bias in domains other than performance bias.
[b]Downgraded twice for imprecision due to the small sample size and the low event rate.

Background

Description of the condition

Pressure ulcers — also known as pressure injuries, pressure sores, decubitus ulcers and bed sores — are localised injuries to the skin or underlying soft tissue (or both), caused by unrelieved pressure, shear or friction (NPIAP 2016). Pressure ulcer severity is generally classified as follows, using the National Pressure Injury Advisory Panel (NPIAP) system (NPIAP 2016).

- Stage 1: intact skin with a local appearance of non-blanchable erythema.
- Stage 2: partial-thickness skin loss with exposed dermis.
- Stage 3: full-thickness skin loss.
- Stage 4: full-thickness skin and tissue loss with visible fascia, muscle, tendon, ligament, cartilage or bone.
- Unstageable pressure injury: full-thickness skin and tissue loss that is obscured by slough or eschar so that the severity of injury cannot be confirmed.
- Deep tissue pressure injury: local injury of persistent, non-blanchable deep red, maroon, purple discolouration or epidermal separation revealing a dark wound bed or blood-filled blister.

The stages described above are consistent with those described in another commonly used system, the International Classification of Diseases for Mortality and Morbidity Statistics (World Health Organization 2019).

Pressure ulcers are complex wounds that are relatively common, affecting people across different care settings. A systematic review found that prevalence estimates for people affected by pressure ulcers in communities of the UK, USA, Ireland and Sweden ranged from 5.6 to 2300 per 10,000 depending on the nature of the population surveyed (Cullum 2016). A subsequent cross-sectional survey of people receiving community health services in one city in the UK estimated that 1.8 people per 10,000 have a pressure ulcer (Gray 2018).

Pressure ulcers confer a heavy burden in terms of personal impact and use of health-service resources. Having a pressure ulcer may impair physical, social and psychological activities (Gorecki 2009). Ulceration impairs health-related quality of life (Essex 2009); can result in longer institution stays (Theisen 2012); and increases the risk of systemic infection (Espejo 2018). There is also substantial impact on

health systems: a 2015 systematic review of 14 studies across a range of care settings in Europe and North America showed that costs related to pressure ulcer treatment ranged from EUR 1.71 to EUR 470.49 per person, per day (Demarré 2015). In the UK, the annual average cost to the National Health Service for managing one person with a pressure ulcer in the community was estimated to be GBP 1400 for a Stage 1 pressure ulcer and more than GBP 8500 for more severe stages (2015/2016 prices; Guest 2018). In Australia, the annual cost of treating pressure ulcers was estimated to be AUD 983 million (95% confidence interval (CI) 815 million to 1151 million) at 2012/2013 prices (Nguyen 2015). The serious consequences of pressure ulceration have led to an intensive focus on their prevention.

Description of the intervention

Pressure ulcers are considered largely preventable. Support surfaces are specialised medical devices designed to relieve or redistribute pressure on the body, or both, in order to prevent pressure ulcers (NPIAP S3I 2007). Types of support surface include, but are not limited to, integrated bed systems, mattresses and overlays (NPIAP S3I 2007).

The NPIAP Support Surface Standards Initiative (S3I) system can be used to classify types of support surface (NPIAP S3I 2007). According to this system, support surfaces may:

- be powered (i.e. require electrical power to function) or non-powered;
- passively redistribute body weight (i.e. reactive pressure redistribution), or mechanically alternate the pressure on the body to reduce the duration of pressure (i.e. active pressure redistribution);
- be made of a range of materials, including but not limited to: air cells, foam materials, fibre materials, gel materials, sheepskin for medical use and water-bags; and
- be constructed of air-filled cells that have small holes on the surface for blowing out air to dry skin (i.e. low-air-loss feature) or have fluid-like characteristics via forcing filtered air through ceramic beads (i.e. air-fluidised feature), or have neither of these features.

Full details of classifications of support surfaces are listed in Appendix 1. A widely used type of support surface is the foam bed or mattress. These beds or mattresses are commonly non-powered and are made of foam materials which confer reactive pressure redistribution over a larger contact area (NPIAP S3I 2007).

How the intervention might work

The aim of using support surfaces to prevent pressure ulceration is to redistribute pressure beneath the body, thereby increasing blood flow to tissues and relieving distortion of the skin and soft tissue (Wounds International 2010). Reactive support surfaces (e.g. foam surfaces) achieve pressure redistribution by passive mechanisms, including immersion (i.e. 'sinking' of the body into a support surface) and envelopment (i.e. conforming of a support surface to the irregularities in the body). These devices distribute the pressure over a greater area, thereby reducing the magnitude of the pressure at specific sites (Clark 2011).

Why it is important to do this review

Support surfaces are widely used for preventing pressure ulcers and are the focus of recommendations in international and national guidelines (EPUAP/NPIAP/PPPIA 2019; NICE 2014). Since the publication of the Cochrane Review, 'Support surfaces for pressure ulcer prevention' (McInnes 2015), there has been a substantial increase in the number of relevant randomised controlled trials published in this area. The NPIAP S3I 2007 support surface-related terms and definitions have also been internationally recognised, and Cochrane has developed new methodological requirements, such as the use of GRADE assessments (Guyatt 2008). These developments necessitate an update of the evidence base.

In considering this evidence update, we took into account the size and complexity of the published review (McInnes 2015), which includes all types of support surface. An alternative approach is to split the review into multiple new titles, each with a narrower focus. We consulted on this splitting option via an international survey in August 2019. The potential new titles suggested were based on clinical use, the new terms and definitions related to support surfaces (NPIAP S3I 2007), a relevant network meta-analysis (Shi 2018a), and current clinical practice guidelines (EPUAP/NPIAP/PPPIA 2019; NICE 2014). We received responses from 29 health professionals involved in pressure ulcer prevention activity in several countries (Australia, Belgium, China, Italy, the Netherlands and the UK). In total, 83% of respondents supported splitting the review into the suggested titles and 17% were unsure (no respondent voted against splitting). The new review titles are as follows.

- Alternating pressure (active) air surfaces for preventing pressure ulcers.
- Foam surfaces for preventing pressure ulcers.
- Reactive air surfaces for preventing pressure ulcers.
- Alternative reactive support surfaces (non-foam and non-air-filled) for preventing pressure ulcers.

We will bring the results of these new reviews together in an overview with a network meta-analysis (Salanti 2012), in order to simultaneously compare all support surfaces and to rank them based on the probabilities of each being the most effective for preventing pressure ulcers. This particular review compares foam beds, mattresses or overlays with any surface.

Objectives

To assess the effects of foam beds, mattresses or overlays compared with any support surface on the incidence of pressure ulcers in any population in any setting.

Methods

Criteria for considering studies for this review

Types of studies

We included published and unpublished randomised controlled trials (RCTs),

including multi-armed studies, cluster-RCTs and cross-over trials, regardless of the language of publication. We also included RCTs with particular designs (factorial design, n-of-1 trials). We excluded studies using quasi-random allocation methods (e.g. alternation).

Types of participants

We included studies in any population, including those defined as being at risk of ulceration, as well as those with existing pressure ulcers at baseline (when the study measured pressure ulcer incidence).

Types of interventions

Eligible studies included foam beds, overlays or mattresses. We included studies where two or more mattresses were used sequentially over time or in combination, where the mattress(es) of interest were included in one of the study arms.

We included studies comparing eligible foam beds, overlays or mattresses against any comparator defined as a support surface.

Comparators could be:

- non-foam surfaces, including: alternating pressure (active) air surfaces such as alternating pressure (or dynamic) air mattresses, reactive air surfaces (e.g. static air overlays, dry flotation mattresses, air-fluidised beds), and non-foam and non-air-filled surfaces (e.g. reactive gel surfaces such as a gel pad used on an operating table, reactive fibre surfaces such as Silicore fibre overlay, reactive water surfaces, reactive sheepskin surfaces such as Australian Medical Sheepskins overlay), or
- a different type of foam surface.

We included studies in which co-interventions (e.g. repositioning) were delivered, provided that co-interventions were the same in all arms of the study (i.e. interventions randomised were the only systematic difference).

Types of outcome measures

We considered the following primary and secondary outcomes. If a study did not report any review-relevant outcomes but was otherwise eligible (i.e. eligible study design, participants and interventions), we contacted the study authors (where possible) to clarify whether they measured a relevant outcome but did not report it. We considered the study as 'awaiting classification' if we could not establish whether it measured an outcome or not. We excluded the study if the study authors confirmed that they did not measure any review-relevant outcomes.

If a study measured an outcome at multiple time points, we considered outcome measures at three months as being of primary interest to this review (Schoonhoven 2007), regardless of the time points specified as being of primary interest by the study. If the study did not report three-month outcome measures, we considered those closest to three months. Where a study only reported a single time point, we considered these data in this review. Where a study did not specify a time point for its outcome measurement, we assumed this was the final duration of follow-up noted.

Primary outcomes

Our primary outcome was pressure ulcer incidence. We recorded two outcome measures (the proportion of participants developing a new pressure ulcer; and time to pressure ulcer incidence), where available. However, we considered the proportion of participants developing a new pressure ulcer as the primary outcome for this review. Our preferred measure was time to pressure ulcer incidence. However, we did not expect it to be reported in many studies. We extracted and analysed time-to-event data but we focused on the binary outcome in our conclusions. We accepted authors' definitions of an incident ulcer regardless of which pressure ulcer severity classification was used to measure or grade new pressure ulcers. We also considered the outcome of pressure ulcer incidence irrespective of whether studies reported ulcers by stages or as a non-stratified value.

We did not consider subjective outcome measures (e.g. 'better' or 'worse' skin condition) as measures of pressure ulcer incidence.

Secondary outcomes

- **Patient support-surface-associated comfort.** We considered patient comfort outcome data in this review only if the evaluation of patient comfort was pre-planned and was systematically conducted across all participants in the same way in a study. The definition and measurement of this outcome varied from one study to another; for example, the proportion of participants who report comfort, or comfort measured by a scale with continuous (categorical) numbers. We planned to include these data with different measurements in separate meta-analyses when possible.

- **All reported adverse events** (measured using surveys or questionnaires, other data capture process or visual analogue scale). We included data where study authors specified a clear method for collecting adverse event data. Where available, we extracted data on all serious and all non-serious adverse events as an outcome. We recorded where it was clear that events were reported at the participant level or whether multiple events per person were reported, in which case appropriate adjustments were required for data clustering (Higgins 2019a). We considered the assessment of any event in general defined as adverse by participants, health professionals, or both.

- **Health-related quality of life** (measured using a standardised generic questionnaire such as EQ-5D (Herdman 2011), 36-item Short Form (SF-36; Ware 1992), or pressure ulcer-specific questionnaires such as the PURPOSE Pressure Ulcer Quality of Life (PU-QOL) questionnaire (Gorecki 2013), at noted time points). We did not include ad hoc measures of quality of life or qualitative interviews of quality of life because these measures were unlikely to be validated.

- **Cost effectiveness:** within-trial cost-effectiveness analysis comparing mean differences in effects with mean cost differences between the two arms. We extracted data on incremental mean cost per incremental gain in benefit (incremental cost-effectiveness ratio (ICER)). We also considered other measures of relative cost-effectiveness (e.g. net monetary benefit, net health benefit).

Search methods for identification of studies

Electronic searches

We searched the following electronic databases to identify reports of relevant clinical trials:

- the Cochrane Wounds Specialised Register (searched 14 November 2019);
- the Cochrane Central Register of Controlled Trials (CENTRAL; 2019, Issue 10) in the Cochrane Library (searched 14 November 2019);
- Ovid MEDLINE including In-Process & Other Non-Indexed Citations (1946 to 14 November 2019);
- Ovid Embase (1974 to 14 November 2019);
- EBSCO CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature; 1937 to 14 November 2019).

The search strategies for the Cochrane Wounds Specialised Register, CENTRAL, Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus can be found in Appendix 2. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2019). We combined the Embase search with the Ovid Embase filter developed by the UK Cochrane Centre (Lefebvre 2019). We combined the CINAHL Plus search with the trial filter developed by Glanville 2019. There were no restrictions with respect to language, date of publication or study setting.

We also searched these clinical trials registries:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (clinicaltrials.gov) (searched 20 November 2019);
- World Health Organization (WHO) International Clinical Trials Registry Platform (https://www.who.int/clinical-trials-registry-platform) (searched 20 November 2019).

Search strategies for clinical trials registries can be found in Appendix 2.

Searching other resources

For previous versions of McInnes 2015, the review authors of McInnes 2015 contacted experts in the field of wound care to enquire about potentially relevant studies that are ongoing, or recently published. In addition, the review authors of McInnes 2015 contacted manufacturers of support surfaces for details of any studies manufacturers were conducting. This approach did not yield any additional studies; therefore, we did not repeat it for this review.

We identified other potentially eligible studies or ancillary publications by searching the reference lists of retrieved included studies, as well as relevant systematic reviews, meta-analyses and health technology assessment reports.

When necessary, we contacted authors of key papers and abstracts to request further information about their trials.

We did not perform a separate search for adverse effects of interventions used. We considered adverse effects described in included studies only.

Data collection and analysis

We carried out data collection and analysis according to the methods stated in the published protocol (Shi 2020), which were based on the *Cochrane Handbook for Systematic Reviews of Interventions* (Li 2019). Changes from the protocol or previous published versions of the review are documented in Differences between protocol and review.

Selection of studies

One review author re-checked the RCTs included in McInnes 2015 for eligibility (CS). Two review authors or researchers (CS and Asmara Jammali-Blasi, or JCD) independently assessed the titles and abstracts of the new search results for relevance using Rayyan (Ouzzani 2016) (Differences between protocol and review), and then independently inspected the full text of all potentially eligible studies. The two review authors or researchers (CS and Asmara Jammali-Blasi, or JCD) resolved disagreements through discussion and by involving another review author, if necessary.

Data extraction and management

One review author checked data from the studies included in McInnes 2015 and extracted additional data where necessary (CS). A second review author or researcher (SR, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) checked any new data extracted.

For new included studies, one review author (CS) independently extracted data and another review author or researcher (SR, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) checked all data (Differences between protocol and review). Any disagreements were resolved through discussion and, if necessary, with the involvement of another review author. Where necessary, we contacted the authors of included studies to clarify data.

We extracted these data using a pre-prepared data extraction form:

- basic characteristics of studies (first author, publication type, publication year and country);
- funding sources;
- care setting;
- characteristics of participants (trial eligibility criteria, average age in each arm or in a study, proportions of participants by gender and participants' baseline skin status);
- support surfaces being compared (including their descriptions);
- details on any co-interventions;
- duration of follow-up;
- the number of participants enrolled;
- the number of participants randomised to each arm;
- the number of participants analysed;
- participant withdrawals with reasons;

- the number of participants developing new ulcers (by ulcer stages where possible);
- data on time to pressure ulceration;
- patient support-surface-associated comfort;
- adverse event outcome data;
- health-related quality of life outcome data; and
- cost-effectiveness outcome data.

We (CS and NC) classified specific support surfaces in the included studies into intervention groups using the NPIAP S3I support surface-related terms and definitions (NPIAP S3I 2007). Therefore, to accurately assign specific support surfaces to intervention groups, we extracted full descriptions of support surfaces from included studies, and when necessary supplemented the information with that from external sources such as other publications about the same support surface, manufacturers' or product websites, and expert clinical opinion (Shi 2018b). If we were unable to define any of specific support surfaces evaluated in an included study, we extracted available data and reported these as additional data outside the main review results.

Assessment of risk of bias in included studies

Two review authors or researchers (CS and SR, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) independently assessed risk of bias of each included study using the Cochrane 'Risk of bias' tool (see Appendix 3). This tool has seven specific domains: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete data (attrition bias), selective outcome reporting (reporting bias), and other issues (Higgins 2017). We assessed performance bias, detection bias, and attrition bias separately for each of the review outcomes (Higgins 2017). We noted that it is often impossible to blind participants and personnel in device trials. In this case, performance bias may be introduced if knowledge of treatment allocation results in deviations from intended interventions, differential use of co-interventions or care between groups not specified in the study protocol that may influence outcomes. We attempted to understand if, and how, included studies compensated for challenges in blinding; for example, implementing strict protocols to maximise consistency of co-interventions between groups to reduce the risk of performance bias. We also noted that pressure ulcer incidence is a subjective outcome. Compared with blinded assessment, non-blinded assessment of subjective outcomes tends to be associated with more optimistic effect estimates of experimental interventions in RCTs (Hróbjartsson 2012). Therefore, we judged non-blinded outcome assessment as being at high risk of detection bias. In this review, we included the issues of differential diagnostic activity and unit of analysis under the domain of 'other issues'. For example, unit of analysis issues occurred where a cluster-randomised trial had been undertaken but analysed at the individual level in the study report.

For the studies included in McInnes 2015, one review author (CS) checked the 'Risk of bias' judgements and, where necessary, updated them. A second review author or researcher (SR, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) checked any updated judgement. We assigned each 'Risk of bias' domain a judgement of high,

low, or unclear risk of bias. We resolved any discrepancy through discussion and by involving another review author where necessary. Where possible, useful and feasible, when a lack of reported information resulted in a judgement of unclear risk of bias, we planned to contact study authors for clarification.

We present our assessment of risk of bias for the proportion of participants developing a new pressure ulcer outcome using two 'Risk of bias' summary figures. One is a summary of bias for each item across all studies, and the second shows a cross-tabulation of each study by all of the 'Risk of bias' items. Once we had given our judgements for all 'Risk of bias' domains, we judged the overall risk of bias for each outcome across studies as:

- low risk of bias, if we judged all domains to be at low risk of bias;
- unclear risk of bias, if we judged one or more domains to be at unclear risk of bias and other domains were at low risk of bias but no domain was at high risk of bias; or
- high risk of bias, as long as we judged one or more domains as being at high risk of bias, or all domains had unclear 'Risk of bias' judgements, as this could substantially reduce confidence in the result.

We resolved any discrepancy between review authors through discussion and by involving another review author where necessary. For studies using cluster randomisation, we planned to consider the risk of bias in relation to recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually randomised studies (Eldridge 2019; Higgins 2019b) (Appendix 3). However, we did not include any studies with a cluster design.

Measures of treatment effect

For meta-analysis of pressure ulcer incidence data, we present the risk ratio (RR) with its 95% confidence interval (CI). For continuous outcome data, we present the mean difference (MD) with 95% CIs for studies that use the same assessment scale. If studies reporting continuous data used different assessment scales, we planned to report the standardised mean difference (SMD) with 95% CIs. However, this was not undertaken in the review.

For time-to-event data (time to pressure ulcer development), we present the hazard ratio (HR) with its 95% CI. If included studies reporting time-to-event data did not report an HR, when feasible we estimated this using other reported outcomes (such as numbers of events) through employing available statistical methods (Parmar 1998; Tierney 2007).

Unit of analysis issues

We noted whether studies presented outcomes at the level of cluster (e.g. ward, research site) or at the level of participants. We also recorded whether the same participant was reported as having multiple pressure ulcers.

Unit of analysis issues may occur if studies randomise at the cluster level but the incidence of pressure ulcers is observed and data are presented and analysed at the level of participants (clustered data). We noted whether data regarding participants within a cluster were (incorrectly) treated as independent within a study, or were analysed using within-cluster analysis methods. If clustered data were incorrectly

analysed, we recorded this as part of the 'Risk of bias' assessment.

If a cluster-RCT was not correctly analysed, we planned to use the following information to adjust for clustering ourselves where possible, in accordance with guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019b).

- The number of clusters randomly assigned to each intervention, or the average (mean) number of participants per cluster.
- Outcome data ignoring the cluster design for the total number of participants.
- Estimate of the intra-cluster (or intra-class) correlation coefficient (ICC).

However, we did not identify any n-of-1 trials in this review. We did not adjust for clustering for the two studies with treatment sessions of each participant as the unit of analysis because they did not report sufficient information to facilitate this (Bliss 1995a; Hoshowsky 1994).

Cross-over trials

For cross-over trials, we only considered outcome data at the first intervention phase (i.e. prior to cross-over) as eligible.

Studies with multiple treatment groups

If a study had more than two eligible study groups, where appropriate we combined results across these arms to make single pair-wise comparisons (Higgins 2019b).

Dealing with missing data

Data are commonly missing from study reports. Reasons for missing data could be the exclusion of participants after randomisation, withdrawal of participants from a study, or loss to follow-up. The exclusion of these data from analysis may break the randomisation and potentially introduces bias.

Where there were missing data and where relevant, we contacted study authors to pose specific queries about these data. In the absence of other information, for pressure ulcer incidence we assumed that participants with missing data did not develop new pressure ulcers for the main analysis (i.e. we added missing data to the denominator but not the numerator). We examined the impact of this assumption through undertaking a sensitivity analysis (see Sensitivity analysis). When a study did not specify the number of randomised participants prior to dropout, we used the available number of participants as the number randomised.

Assessment of heterogeneity

Assessing heterogeneity can be a complex, multifaceted process. Firstly, we considered clinical and methodological heterogeneity; that is, the extent to which the included studies varied in terms of participant, intervention, outcome, and other characteristics including duration of follow-up, clinical settings, and overall study-level 'Risk of bias' judgement (Deeks 2019). In terms of the duration of follow-up, in order to assess the relevant heterogeneity, we recorded and categorised assessment of outcome measures as follows:

- up to eight weeks (short-term);

- more than eight weeks to 16 weeks (medium-term); and
- more than 16 weeks (long-term).

We supplemented this assessment of clinical and methodological heterogeneity with information regarding statistical heterogeneity assessed using the Chi^2 test. We considered a P value of less than 0.10 to indicate statistically significant heterogeneity given that the Chi^2 test has low power, particularly in the case where studies included in a meta-analysis have a small sample size. We carried out this statistical assessment in conjunction with the I^2 statistic (Higgins 2003), and the use of prediction intervals for random-effects meta-analyses (Borenstein 2017; Riley 2011).

The I^2 statistic is the percentage of total variation across studies due to heterogeneity rather than chance (Higgins 2003). Very broadly, we considered that I^2 values of 25% or less may indicate a low level of heterogeneity and values of 75% or more may indicate very high heterogeneity (Higgins 2003). For random-effects models where the meta-analysis has more than 10 included studies and no clear funnel plot asymmetry, we also planned to present 95% prediction intervals (Deeks 2019). We planned to calculate prediction intervals following methods proposed by Borenstein 2017.

Random-effects analyses produce an average treatment effect, with 95% confidence intervals indicating where the true population average value is likely to lie. Prediction intervals quantify variation away from this average due to between-study heterogeneity. The interval conveys where a future study treatment effect estimate is likely to fall based on the data analysed to date (Riley 2011). Prediction intervals are always wider than confidence intervals (Riley 2011).

It is important to note that prediction intervals will reflect heterogeneity of any source, including from methodological issues as well as clinical variation. For this reason, some authors have suggested that prediction intervals are best calculated for studies at low risk of bias to ensure intervals that have meaningful clinical interpretation (Riley 2011). We had planned to calculate prediction intervals for all studies to assess heterogeneity and then to explore the impact of risk of bias in subgroup analysis stratified by study risk of bias assessment as detailed below. However, we did not calculate any prediction intervals because all conducted meta-analyses contained fewer than 10 studies.

Assessment of reporting biases

We followed the systematic framework recommended by Page 2019 to assess risk of bias due to missing results (non-reporting bias) in the meta-analysis of pressure ulcer incidence data. To make an overall judgement about risk of bias due to missing results we:

- identified whether pressure ulcer incidence data were unavailable by comparing the details of outcomes in trials registers, protocols or statistical analysis plans (if available) with reported results. If the above information sources were unavailable, we compared outcomes in the conference abstracts or in the methods section of the publication, or both, with the reported results. If we found non-reporting of study results, we then judged whether the non-reporting was associated with the nature of findings by using the 'Outcome Reporting Bias In Trials' (ORBIT) system (Kirkham 2018).

- assessed the influence of definitely missing pressure ulcer incidence data on meta-analysis.
- assessed the likelihood of bias where a study had been conducted but not reported in any form. For this assessment, we considered whether the literature search was comprehensive and planned to produce a funnel plot for meta-analysis for seeking more evidence about the extent of missing results, provided there were at least 10 included studies (Peters 2008; Salanti 2014).

However, we did not produce a funnel plot for any meta-analysis because all analyses in this review had fewer than 10 included studies.

Data synthesis

We summarised the included studies narratively and synthesised included data using meta-analysis where applicable. We structured comparisons according to type of comparator and then by outcomes, ordered by follow-up period.

We considered clinical and methodological heterogeneity and undertook pooling when studies appeared appropriately similar in terms of participants, support surfaces and outcome type. Where statistical synthesis of data from more than one study was not possible or considered inappropriate, we conducted a narrative review of eligible studies.

Once the decision to pool was made, we used a random-effects model, which estimated an underlying average treatment effect from studies. Conducting meta-analysis with a fixed-effect model in the presence of even minor heterogeneity may provide overly narrow confidence intervals. We used the Chi^2 test and I^2 statistic to quantify heterogeneity but not to guide choice of model for meta-analysis (Borenstein 2009). We exercised caution when meta-analysed data were at risk of small-study effects because use of a random-effects model may be unsuitable in this situation. In this case, or where there were other reasons to question the choice of a fixed-effect or random-effects model, we assessed the impact of the approach using sensitivity analyses to compare results from alternate models (Thompson 1999).

We performed meta-analyses largely using Review Manager 5.4 (Review Manager 2020). We presented data using forest plots where possible. For dichotomous outcomes, we presented the summary estimate as a RR with 95% CI. Where continuous outcomes were measured, we presented the MD with 95% CIs. We planned to report SMD estimates where studies measured the same outcome using different methods. For time-to-event data, we presented the summary estimates as HRs with 95% CIs.

Subgroup analysis and investigation of heterogeneity

Investigation of heterogeneity

When important heterogeneity occurred, we planned to follow steps proposed by Cipriani 2013 and Deeks 2019 to investigate further:

- check the data extraction and data entry for errors and possible outlying studies;
- if outliers existed, perform sensitivity analysis by removing them; and
- if heterogeneity was still present, we planned to perform subgroup analyses for

study-level characteristics (see below) in order to explain heterogeneity as far as possible. However, we did not undertake any subgroup analysis because meta-analyses in this review included fewer than 10 studies.

Subgroup analysis

We investigated heterogeneity using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2019). We planned to perform subgroup analyses for binary and categorical factors (or meta-regression for continuous factors) to determine whether the size of treatment effects was influenced by these four study-level characteristics:

- risk of bias (binary: low or unclear risk of bias; and high risk of bias (Schulz 1995));
- settings (categorical: acute care and other hospital settings; long-term care settings; operating theatre setting; and intensive care unit);
- baseline skin status (categorical: participants at risk, of mixed skin status or non-reporting; non-blanchable erythema; existing ulcers of Stage 2 or serious (Shi 2018c)); and
- follow-up duration (continuous).

We did not perform subgroup analysis or meta-regression when the number of studies included in the meta-analysis was not reasonable (i.e. fewer than 10).

We planned to compare subgroup findings using the 'Test for Subgroup Differences' in Review Manager 5.4 (Review Manager 2020).

Sensitivity analysis

We conducted sensitivity analyses for the following factors, to assess the robustness of meta-analysis of data on pressure ulcer incidence.

- Impact of the selection of pressure ulcer incidence outcome measure. The proportion of participants developing a new pressure ulcer was the primary outcome measure for this review but we also analysed time to pressure ulcer development, where data were available.
- Impact of missing data. The primary analysis assumed that participants with missing data did not develop new pressure ulcers. We also analysed pressure ulcer incidence by only including data for the participants for whom we had endpoint data (complete cases). We noted that when a study only had complete case data (i.e. missing data or the numbers of participants randomised were not reported), complete case data were considered in the related main analysis (see Differences between protocol and review).
- Impact of altering the effects model used. We used a random-effects model for the main analysis followed by a fixed-effect analysis.

Summary of findings and assessment of the certainty of the evidence

We presented the main, pooled results of the review in 'Summary of findings' tables, which we created using GRADEpro GDT software. These tables present key information concerning the certainty of evidence, the magnitude of the effects of the

interventions examined and the sum of available data for the main outcomes (Schünemann 2019). The tables also include an overall grading of the certainty of the evidence associated with each of the main outcomes that we assessed using the GRADE approach. The GRADE approach defines the certainty of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest.

The GRADE assessment involves consideration of five factors: within-trial risk of bias, directness of evidence, heterogeneity, precision of effect estimates, and risk of publication bias (Schünemann 2019). The certainty of evidence can be assessed as being high, moderate, low or very low; RCT evidence has the potential to be high-certainty. We did not downgrade the certainty of evidence for the risk of bias factor in a specific circumstance. That is if the blinding of participants and personnel was the only domain resulting in our judgement of overall high risk of bias for the included studies; however for these studies it was impossible to blind participants and personnel. When downgrading for imprecision, we followed the methods described in Guyatt 2011: either considering both the optimal information size (OIS) and the 95% CI of each meta-analysis if they were estimable; or considering the sample size, the number of events and other effectiveness indicators if the calculation of OIS and undertaking a meta-analysis were not applicable. Where necessary, we used the GRADE 'default' minimum important difference values (RR = 1.25 and 0.75) as the thresholds to judge if a 95% CI was wide (imprecise) so as to include the possibility of clinically important harm and benefit (Guyatt 2011).

We presented a separate 'Summary of findings' table for all but two comparisons evaluated in this review. The two exceptions were the comparison of foam surfaces versus another type of foam surface, and the comparison of foam surfaces versus reactive water surfaces; see Differences between protocol and review. We present these outcomes in the 'Summary of findings' tables:

- proportion of participants developing a new pressure ulcer;
- time to pressure ulcer development;
- support-surface-associated patient comfort;
- all reported adverse events;
- health-related quality of life; and
- cost-effectiveness.

We prioritised the time points and method of outcome measurement specified in Types of outcome measures for presentation in ‘Summary of findings’ tables. Where we did not pool data for some outcomes within a comparison, we conducted a GRADE assessment for each of these outcomes and presented these assessments in a narrative format in 'Summary of findings' tables (see Differences between protocol and review).

Results

Description of studies

See Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.

Results of the search

The electronic searches identified 1624 records. including 1164 from electronic databases and 460 from trial registries. We excluded 218 duplicate records and screened 1406 records, of which 233 were identified as potentially eligible and obtained as full-text. Following full-text screening, we considered 42 records of 28 studies eligible for inclusion in this review (Berthe 2007; Bliss 1995a; Bueno de Camargo 2018; Collier 1996; Feuchtinger 2006; Gray 1994; Gray 2000; Gunningberg 2000; Hofman 1994; Hoshowsky 1994; Kemp 1993; Laurent 1998; Nixon 2019; Ozyurek 2015; Park 2017; Rosenthal 2003; Russell 2003a; Santy 1994; Sauvage 2017; Schultz 1999; Stapleton 1986; Takala 1996; Van Leen 2011; Van Leen 2013; Van Leen 2018; Vyhlidal 1997; Whitney 1984; Whittingham 1999). Of these studies, Bueno de Camargo 2018 was identified via backward searching the trial registry record NCT02844166 (see Bueno de Camargo 2018).

From other resources, we identified one further eligible study, Allman 1987, by scanning the reference lists of the 14 systematic reviews or meta-analyses that were identified from electronic searches (Chou 2013; Huang 2013; McGinnis 2011; McInnes 2015; McInnes 2018; Mistiaen 2010a; De Oliveira 2017; Rae 2018; Reddy 2006; Reddy 2008; Serraes 2018; Shi 2018a; Smith 2013; Yao 2018), as well as the clinical practice guidelines listed in Searching other resources.

In total we included 29 studies in the review, of which one was an unpublished report (Santy 1994), and two were conference abstracts (Laurent 1998; Whittingham 1999). See Figure 1.

Included studies

Types of studies

Of the 29 included RCTs, 25 had a parallel group design: 21 with two arms, one with three arms (Stapleton 1986), two with six arms (Santy 1994; Whittingham 1999), and one with eight arms (Collier 1996). Four studies had particular design features:

- one study appeared to be a multi-arm, multi-stage trial design with eight arms, of which seven were randomised and eligible for this review (Bliss 1995a);
- one study was a split body design (that is, it randomly allocated different support surfaces to either the right or left half of the body of the same person) and three of its six arms included foam surfaces (Hoshowsky 1994);
- one study applied 2 × 2 factorial design (Laurent 1998), including the comparison of foam mattresses versus standard hospital surfaces; and
- one study used cross-over design (Van Leen 2013).

Of the 29 studies, six were conducted at more than one research site (Kemp 1993; Nixon 2019; Rosenthal 2003; Russell 2003a; Sauvage 2017; Van Leen 2018). Except for one study conducted in South Korea (Park 2017), and one in Turkey (Ozyurek 2015), all of the included studies were conducted in high-income and upper-middle-income economies in Europe and North or South America, including: Belgium (Berthe 2007; Laurent 1998), Brazil (Bueno de Camargo 2018), Finland (Takala 1996), France (Sauvage 2017), Germany (Feuchtinger 2006), the Netherlands (Hofman 1994; Van Leen 2011; Van Leen 2013; Van Leen 2018), Sweden (Gunningberg 2000), the UK (Bliss 1995a; Collier 1996; Gray 1994; Gray 2000; Nixon 2019; Russell 2003a; Santy 1994; Stapleton 1986; Whittingham 1999) and the

USA (Allman 1987; Hoshowsky 1994; Kemp 1993; Rosenthal 2003; Schultz 1999; Vyhlidal 1997; Whitney 1984).

The included studies were published between 1986 and 2018. Of the 26 studies that clearly stated duration of follow-up, the median was 14.5 days (range: 5.0 days to 12.0 months).

Types of participants

Age and sex at baseline

The 29 included studies enrolled a total of 9566 participants (median study sample size: 101 participants; range: 40 to 2029). The average participant age was specified for 25 studies and ranged between 47.0 and 85.3 years (median: 76 years). The sex of the participants was specified in 24 studies; and within these 2659 (43.4%) of participants were male and 3466 (56.6%) were female.

Skin status at baseline

Of the 29 studies, 25 (8601 participants) recruited people at risk of having a new ulcer with risk assessed largely using the Waterlow, Norton or Braden scales. In 21 of these studies, 5512 (64.1%) participants were free of pressure ulcers at baseline. In four studies, 3089 (35.9%) participants with superficial ulcers were enrolled (Bliss 1995a; Nixon 2019; Santy 1994; Whitney 1984). Two studies (817 participants; Hoshowsky 1994; Laurent 1998) did not specify the skin status at baseline; and two studies (148 participants; Allman 1987; Rosenthal 2003) recruited people with severe full-thickness pressure ulcers alone.

Care settings

Participants were recruited from a variety of settings, including:

- a mixture of secondary and community in-patient facilities (n = 2; Kemp 1993; Nixon 2019);
- acute care settings (including accident and emergency departments, and hospitals in general) (n = 16; Allman 1987; Berthe 2007; Bliss 1995a; Collier 1996; Gray 1994; Gray 2000; Gunningberg 2000; Hofman 1994; Hoshowsky 1994; Laurent 1998; Park 2017; Russell 2003a; Santy 1994; Stapleton 1986; Vyhlidal 1997; Whitney 1984);
- intensive care units (n = 3; Bueno de Camargo 2018; Ozyurek 2015; Takala 1996);
- operating rooms (n = 2; Feuchtinger 2006; Schultz 1999); and
- community and long-term care settings (including nursing homes, long-term facilities, geriatric units) (n = 6; Rosenthal 2003; Sauvage 2017; Van Leen 2011; Van Leen 2013; Van Leen 2018; Whittingham 1999).

Types of interventions

The studies investigated a wide range of foam surfaces. Of the 29 studies, 14 described characteristics of foam surfaces used (e.g. foam thickness, foam density, viscoelastic foam; Bueno de Camargo 2018; Collier 1996; Gray 1994; Gray 2000; Gunningberg 2000; Hofman 1994; Laurent 1998; Nixon 2019; Park 2017; Santy 1994; Sauvage 2017; Takala 1996; Vyhlidal 1997; Whittingham 1999) and 15 did not specify the types of foam surfaces they used.

Full details of foam surfaces and comparators are listed in Appendix 4 and in results below. Eight studies used comparator group surfaces defined by the study authors as 'standard hospital surfaces' that could not be classified further using the NPIAP S3I support surface terms and definitions (Berthe 2007; Feuchtinger 2006; Gunningberg 2000; Hofman 1994; Laurent 1998; Park 2017; Russell 2003a; Schultz 1999). Of these eight studies, three did not specify what types of surfaces the 'standard hospital surfaces' were (Berthe 2007; Laurent 1998; Park 2017), whilst five stated that the 'standard hospital surfaces' used included a variety of support surface options such as King's Fund, Softfoam, Transfoam, gel pads and foam egg crate mattresses. One study (206 participants) used a type of reactive surface (Bedcare; Sense Textile's-Hertogenbosch) on top of foam surfaces in comparison with foam surfaces (Van Leen 2018).

Twelve studies specified co-interventions they applied (e.g. repositioning, cushions) (Allman 1987; Bueno de Camargo 2018; Hofman 1994; Ozyurek 2015; Park 2017; Rosenthal 2003; Schultz 1999; Van Leen 2011; Van Leen 2013; Van Leen 2018; Vyhlidal 1997; Whitney 1984). All twelve stated or indicated that the same co-interventions were applied in all study groups.

Funding sources

Of the 29 included studies, 19 specified the details of funding sources. Eleven of these were completely or partly funded by industry or received mattresses under evaluation from industries (Allman 1987; Bliss 1995a; Bueno de Camargo 2018; Gray 1994; Gray 2000; Gunningberg 2000; Russell 2003a; Schultz 1999; Takala 1996; Van Leen 2018; Vyhlidal 1997); four were supported by public funding (Nixon 2019; Ozyurek 2015; Santy 1994; Stapleton 1986); one was funded by charity foundations (Kemp 1993); and three noted no funding support (Berthe 2007; Laurent 1998; Van Leen 2011).

Excluded studies

We excluded 142 studies (with 177 records). The main reasons for these 142 exclusions were: irrelevant and ineligible interventions (55 studies); ineligible study design (e.g. non-RCT, reviews, commentary articles; 52 studies); studies focused on the treatment rather than prevention of pressure ulcers (20 studies); incorrect randomisation and non-randomised methods (eight studies); studies with ineligible outcomes (four studies); clinical trials that were withdrawn (two studies; NCT02634892; NCT02735135); and ineligible participants (healthy subjects; one study). We also identified eight duplicates in screening full texts (see Figure 1).

Ongoing studies

We did not identify any ongoing studies.

Studies awaiting classification

There were six studies (six records) for which we could not make eligibility decisions. For Gardner 2008, we were unable to determine whether the study used foam surfaces. For the remaining five studies, we were unable to obtain the full-texts (in part due to more limited access to intra-library loans during the COVID-19 period) despite extensive efforts (Chaloner 2000b; Henn 2004; Knight 1999; Mastrangelo 2010a; Melland 1998).

Risk of bias in included studies

We summarise 'Risk of bias' assessments for the primary outcome of this review in Figure 2 and Figure 3.

We judged 12 of the 29 studies to have an unclear overall risk of bias for the primary outcome (Allman 1987; Berthe 2007; Feuchtinger 2006; Gray 1994; Gray 2000; Gunningberg 2000; Kemp 1993; Rosenthal 2003; Schultz 1999; Van Leen 2011; Van Leen 2013; Vyhlidal 1997). We judged all the remaining 17 studies as having findings at a high overall risk of bias, of which two had an unclear risk of bias judgements for all domains (Stapleton 1986; Whittingham 1999), and 15 had one or more domains with a high risk of bias judgement (Bliss 1995a; Bueno de Camargo 2018; Collier 1996; Hofman 1994; Hoshowsky 1994; Laurent 1998; Nixon 2019; Ozyurek 2015; Park 2017; Russell 2003a; Santy 1994; Sauvage 2017; Takala 1996; Van Leen 2018; Whitney 1984). Of these 15 studies, 10 had a high risk of bias judgement for the primary outcome in the domains of blinding of participants and personnel, blinding of outcome assessment, or both (Bueno de Camargo 2018; Collier 1996; Hofman 1994; Hoshowsky 1994; Laurent 1998; Nixon 2019; Russell 2003a; Sauvage 2017; Takala 1996; Whitney 1984).

Publication bias

We ran a comprehensive search and were able to locate one eligible study from other resources. We considered the risk of having missed published reports to be low. We were unable to assess for the risk of non-publication of studies with negative findings as we could not present funnel plots given the small number of included studies in each analysis.

Effects of interventions

See Summary of findings table 1; Summary of findings table 2; Summary of findings table 3; Summary of findings table 4; Summary of findings table 5.

Unless otherwise stated, random-effects analysis was used throughout. Each pooled result presented is an average effect, rather than a common effect and should be interpreted as such.

We have not reported data from the nine studies with comparator surfaces that we could not classify in the main body of the results (Berthe 2007; Feuchtinger 2006; Gunningberg 2000; Hofman 1994; Laurent 1998; Park 2017; Russell 2003a; Schultz 1999; Van Leen 2018). For completeness, we summarise the results of these studies in Appendix 5.

We performed data analyses for the following comparisons and outcomes. Where applicable, we performed pre-specified sensitivity analyses as noted in Sensitivity analysis.

Comparison 1: Foam surfaces versus alternating pressure (active) air surfaces (six studies, 2427 participants)

One study, Bliss 1995a, randomised participants to three types of foam mattresses (in three individual trial arms) against the relevant comparison, which was a type of alternating pressure (active) air surface. However, this study and Whitney 1984 (in total 180 participants) reported no outcomes directly relevant to this review so

provided no analysable data. The remaining studies compared foam surfaces with an alternating pressure (active) air surface.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration median 90 days, minimum 30 days, maximum 6 months)

Four studies (2247 participants) reported data for this outcome that were pooled (Nixon 2019; Rosenthal 2003; Sauvage 2017; Stapleton 1986). Foam surfaces (117/1122 (10.4%)) may increase the proportion of participants developing incident pressure ulcers compared with alternating pressure (active) air surfaces (83/1125 (7.4%)). The RR is 1.59 (95% CI 0.86 to 2.95; I^2 = 63%; Analysis 1.1). The evidence is of low certainty. Evidence certainty was downgraded once for risk of bias (two studies contributing 50% weight in the meta-analysis had either one domain other than performance bias at high risk of bias or all domains at unclear risk of bias; two studies contributing 50% of weight in the meta-analysis had domains other than performance bias at low or unclear risk of bias), and once for imprecision as, despite the fact that the OIS was met, the wide confidence interval crossed RR = 1.25.

Subgroup analysis

We considered the studies included in Analysis 1.1 heterogeneous in terms of all pre-specified subgroup factors (overall 'risk of bias', care settings, skin status at baseline, and follow-up) and there was some indication of statistical heterogeneity (Chi^2 test P value = 0.07; Tau^2 = 0.18; I^2 = 63%). We noticed that, of the four studies, Sauvage 2017 reported a greater treatment effect than the other three, and that once that study data were removed, I^2 was reduced from 63% to 0% but the overall estimate remained consistent with the main analysis (RR 1.27, 95% CI 0.97 to 1.67; Chi^2 test P value = 0.83; Tau^2 = 0.00; I^2 = 0%). Of the four studies, Sauvage 2017 was different from others in terms of care settings: Sauvage 2017 was conducted at long-term care settings whilst others studies were conducted in acute care settings. However, as noted in Subgroup analysis and investigation of heterogeneity, because there were fewer than 10 studies, we did not undertake a subgroup analysis.

Sensitivity analyses

We performed sensitivity analyses for the following factors but did not use complete case data for sensitivity analysis because the four included studies did not report missing data.

- ***Sensitivity analysis with fixed-effect (rather than random-effects) model*** . The use of a fixed-effect model resulted in a RR of 1.41 (95% CI 1.08 to 1.83; I^2 = 63%). The results suggest that the effect size of our outcome of interest is sensitive to the type of effect model chosen and there is a possibility that foam surfaces increase the proportion of participants developing a new pressure ulcer in comparison with alternating pressure (active) air surfaces (Appendix 6).
- ***Post-hoc sensitivity analysis of using pressure ulcer incidence data from*** Nixon 2019 ***only*** . In Analysis 1.1, Nixon 2019 was the largest study (with data for 2029 participants) and was the only study having all domains other than performance bias at low risk of bias for this outcome. Using pressure ulcer incidence data from Nixon 2019 made little difference to the pooled effect estimate (RR 1.29, 95% CI 0.96 to 1.74; I^2 = 0%; Appendix 6).

- ***Sensitivity analysis with time to pressure ulcer development as pressure ulcer incidence measure (median follow-up duration 60 days, minimum 30 days, maximum 90 days)*** . Two studies (2105 participants) reported this outcome measure (Nixon 2019; Sauvage 2017), and these data were pooled. Analysis 1.2 resulted in a HR of 2.46 (95% CI 0.61 to 9.88; I^2 = 86%). It is uncertain whether there is a difference in the risk of developing a new pressure ulcer, over 60 days' follow-up, between foam surfaces and alternating pressure (active) air surfaces. Evidence is of very low certainty, downgraded once for high risk of bias in one study with 40% of analysis weight, twice for substantial inconsistency, and once for imprecision (Appendix 6).

Secondary outcomes

Support-surface-associated patient comfort (follow-up duration 30 days)

Only Sauvage 2017 (76 participants) reported this outcome, defined by the study authors as the perception of patient comfort and measured using a satisfaction questionnaire. Sauvage 2017 reported no significant difference in the overall satisfaction between study groups (P = 0.21); no other information was reported. We are uncertain whether there is any difference between foam surfaces and alternating pressure (active) air surfaces in positive patient comfort responses. Evidence is of very low certainty, downgraded twice for high risk of detection bias, and once for imprecision.

All reported adverse events (follow-up duration minimum 30 days, maximum 6 months)

Three studies (2181 participants) reported this outcome (Nixon 2019; Rosenthal 2003; Sauvage 2017). We did not pool these data as the definitions of adverse events varied between studies (Table 1). It is uncertain if there is any difference in adverse effects between foam surfaces and alternating pressure (active) air surfaces. Evidence is of very low certainty, downgraded once for unclear risk of bias in two studies and twice for inconsistency.

Health-related quality of life (follow-up duration 90 days)

Only Nixon 2019 (2029 participants) reported health-related quality of life, measured using the EQ-5D-5L (with 267 participants only) and PU-QoL-UI (with 233 participants only). It is uncertain if there is a difference in health-related quality of life (measured using either the EQ-5D-5L or the PU-QoL-UI) at 90 days follow-up in those allocated to foam surfaces or alternating pressure (active) air surfaces (low-certainty evidence). Nixon 2019 reported a MD in the 90-day EQ-5D-5L of 0.00 (95% CI -0.05 to 0.05) between 149 participants using foam surfaces and 118 using alternating pressure (active) air surfaces; and a MD in 90-day PU-QoL-UI of 0.00 (95% CI -0.03 to 0.03) between 126 participants using foam surfaces and 107 using alternating pressure (active) air surfaces (Analysis 1.3). Evidence certainty was downgraded twice for imprecision due to small sample sizes for this outcome.

Cost-effectiveness (follow-up duration 90 days)

Only Nixon 2019 (2029 participants) reported the incremental cost per quality-adjusted life-year (QALY) gained based on within-trial analyses. Moderate-certainty evidence suggests that alternating pressure (active) air surfaces have a 99% probability of being cost-effective at a threshold of GBP 20,000 compared with foam surfaces. Evidence certainty was downgraded once for imprecision for the EQ-5D-5L

outcome from which QALY scores were calculated.

Comparison 2: Foam surfaces versus reactive air surfaces (four studies, 236 participants)

Four studies (236 participants) compared foam surfaces with reactive air surfaces (Allman 1987; Takala 1996; Van Leen 2011; Van Leen 2013). Of these studies, Allman 1987 applied a foam mattress on top of an alternating pressure (active) air surface in comparison with a reactive air surface that had an air-fluidised feature.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration minimum 13 days, maximum six months)

All four studies (236 participants) reported this outcome and the data of 229 participants were available for analysis. Foam surfaces (32/116 (27.6%)) may increase the proportion of participants developing a new pressure ulcer compared with reactive air surfaces (12/113 (10.6%); low-certainty evidence). The RR is 2.40 (95% CI 1.04 to 5.54; I^2 = 25%; Analysis 2.1). Evidence certainty was downgraded once for risk of bias (one study contributing 8% weight in the meta-analysis had domains other than performance bias at high risk of bias and all the remaining studies had domains other than performance bias at low or unclear risk of bias) and once for imprecision as, despite the fact that the OIS was met, the 95% CI crossed RR = 1.25.

The included studies did not report data on time to pressure ulcer incidence.

Subgroup analysis

We considered the studies in Analysis 2.1 heterogenous in terms of follow-up durations, care settings, and overall 'risk of bias' and there was an indication of small statistical heterogeneity (Chi^2 test P = 0.26; Tau^2 = 0.21; I^2 = 25%). We did not perform any pre-specified subgroup analysis because, as noted in Subgroup analysis and investigation of heterogeneity, the number of included studies was fewer than 10, meaning it would be difficult to meaningfully interpret the results.

Sensitivity analyses

- ***Sensitivity analysis with fixed-effect (rather than random-effects) model*** . The use of a fixed-effect model resulted in a RR of 2.47 (95% CI 1.40 to 4.38; I^2 = 25%). The result remained consistent with the main analysis (Appendix 6).

Secondary outcomes

Support-surface-associated patient comfort (follow-up duration 13 days)

Only Allman 1987 (72 participants) reported this outcome in which participants were asked to choose a response to a comfort-related question from categories: 'Very comfortable', 'Comfortable', 'Uncomfortable', or 'Very uncomfortable'. It is uncertain if there is a difference in patient comfort responses between those using foam surfaces on top of an alternating pressure (active) air surface and those using reactive air surfaces (P = 0.04; very low-certainty evidence). Evidence certainty was downgraded once for unclear risk of bias, and twice for imprecision due to the small sample size.

All reported adverse events (follow-up duration 13 days)

Only Allman 1987 (72 participants) reported this outcome (see Table 1). It is uncertain if there is a difference in adverse events between foam surfaces and reactive air surfaces (very low-certainty evidence). Evidence certainty was downgraded once for unclear risk of bias, and twice for imprecision due to the small sample size.

Health-related quality of life

Not reported.

Cost-effectiveness

Not reported.

Comparison 3: Foam surfaces versus reactive fibre surfaces (two studies, 228 participants)

Bliss 1995a and Stapleton 1986 compared foam surfaces with reactive fibre surfaces. Bliss 1995a had no outcomes directly relevant to this review and so none of the data were analysable.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration unspecified)

Stapleton 1986 (68 participants) reported data for this outcome. It is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between foam surfaces (14/34 (41.2%)) and reactive fibre surfaces (12/34 (35.3%)). The RR is 1.17 (95% CI 0.64 to 2.14; Analysis 3.1). The evidence is of very low certainty, downgraded twice for unclear risk of bias in all domains, and twice for imprecision as the OIS was not met and the wide 95% CI crossed RRs = 0.75 and 1.25, failing to exclude important benefits or harms.

The included study did not report data on time to pressure ulcer incidence.

Secondary outcomes

None reported.

Comparison 4: Foam surfaces versus reactive gel surfaces (one study, 135 participants)

Hoshowsky 1994 was a study with a split body design. It compared foam surfaces with two study arms that both applied reactive gel surfaces on top of another type of surface. We combined these into a single study arm.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration unspecified)

Hoshowsky 1994 (135 participants) reported this outcome but indicated that no pressure ulcers developed. It is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between foam surfaces and reactive gel surfaces. The evidence is of very low certainty, downgraded twice for high risk of bias in domains other than performance bias, and twice for imprecision due to the small sample size and the low event rate.

The included study did not report data on time to pressure ulcer incidence.

Secondary outcomes

None reported.

Comparison 5: Foam surfaces versus reactive foam and gel surfaces (one study, 91 participants)

Using a split body design, Hoshowsky 1994 compared foam surfaces with reactive foam and gel surfaces.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration unspecified)

Hoshowsky 1994 (91 participants) reported this outcome but indicated that no pressure ulcers developed. It is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between foam surfaces and reactive foam and gel surfaces. The evidence is of very low certainty, downgraded twice for high risk of bias in domains other than performance bias, and twice for imprecision due to the small sample size and the low event rate.

The included study did not report data on time to pressure ulcer incidence.

Secondary outcomes

None reported.

Comparison 6: Foam surfaces versus reactive water surfaces (one study, 117 participants)

Bliss 1995a compared foam surfaces with reactive water surfaces but reported no outcomes directly relevant to this review and so none of the data were analysable.

Comparison 7: Comparison between two types of foam surface (nine studies, 1764 participants)

Nine studies compared two different types of foam surface (Bueno de Camargo 2018; Collier 1996; Gray 1994; Gray 2000; Kemp 1993; Ozyurek 2015; Santy 1994; Vyhlidal 1997; Whittingham 1999). Of these, two studies compared six types of foam surfaces (Santy 1994; Whittingham 1999), and one included eight foam surfaces (Collier 1996).

We did not pool data from the nine studies as it was not possible to interpret this as a single comparison. We summarised study findings narratively below with key outcome data presented in Table 2 and Table 3.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration minimum 10 days, maximum 12 months or unspecified)

Six studies (733 participants) reported data for this outcome (Bueno de Camargo 2018; Collier 1996; Gray 2000; Kemp 1993; Ozyurek 2015; Vyhlidal 1997; see Table 2). Overall, it is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between the two types of foam surface. Evidence is

of very low certainty, downgraded once for risk of bias (three studies contributing half the data for this outcome were at high risk of bias and the remaining three studies were at unclear risk of bias in at least one domain), twice for substantial inconsistency that we could not explain, and once for imprecision as the sample sizes were small for all six studies.

Two studies (146 participants) reported time to pressure ulcer development (follow-up duration 11.5 days and one month). Bueno de Camargo 2018 (62 participants) reported an unadjusted HR of 0.33 (95% CI 0.17 to 0.64) for a comparison of viscoelastic foam surfaces with a density of 40 to 60 kg/m^3 versus foam surfaces with a density of 33 kg/m^3 in an intensive care unit setting. Kemp 1993 (84 participants) reported an adjusted HR of 0.40 (95% CI 0.20 to 0.80) for a comparison of solid foam surfaces versus convoluted foam surfaces at acute care and long-term care settings. See Table 2. Overall, low-certainty evidence suggests that viscoelastic foam surfaces with a density of 40 to 60 kg/m^3 and solid foam surfaces may decrease the risk of developing incident pressure ulcers at any point over one month's follow-up compared with the control foam surfaces. Evidence certainty was downgraded once for risk of bias (the two studies were at either high or unclear risk of bias) and once for imprecision as both studies were very small.

Secondary outcomes

Support-surface-associated patient comfort (follow-up duration minimum 10 days, maximum 12 months or unspecified)

Four studies (669 participants) reported this outcome (Collier 1996; Gray 1994; Gray 2000; Whittingham 1999). The studies report a range of different measures and outcome data cannot be easily interpreted (see Table 3). We are uncertain if there is a difference in positive patient comfort responses between different types of foam surface. Evidence is of very low certainty, downgraded once for risk of bias (two studies were at high risk of bias and another two studies were at unclear risk of bias), twice for substantial inconsistency, and once for imprecision due to small sample sizes in these studies.

All reported adverse events

Not reported.

Health-related quality of life

Not reported.

Cost-effectiveness

Not reported.

Discussion

Summary of main results

We report evidence from 29 RCTs on the effects of foam surfaces compared with any alternative support surface on the incidence of pressure ulcers in any population in any setting. We did not analyse data reported in the nine studies that compared foam surfaces with surfaces that could not be classified. We analysed data for seven

comparisons in the review and we summarise key findings for these comparisons below.

- **Foam surfaces versus alternating pressure (active) air surfaces**. Foam surfaces may increase the proportion of people developing incident pressure ulcers compared with alternating pressure (active) air surfaces (four studies with 2247 participants; low-certainty evidence). It is uncertain whether there is any difference in support-surface-associated patient comfort between these types of support surfaces (one study; 76 participants), as well as in the number of all reported adverse events (three studies; 2181 participants). It is uncertain if there is a difference in health-related quality of life (measured using either the EQ-5D-5L or the PU-QoL-UI) at 90 days' follow-up between these surfaces (one study with 2029 participants; low-certainty evidence). We found moderate-certainty cost-effectiveness evidence that alternating pressure (active) air surfaces are probably more cost-effective than foam surfaces.
- **Foam surfaces versus reactive air surfaces**. Foam surfaces may increase the proportion of participants developing a new pressure ulcer compared with reactive air surfaces (four studies with 229 participants; low-certainty evidence). It is uncertain if there is a difference in patient comfort responses and in adverse event rates between people using reactive air surfaces and those using foam surfaces on top of alternating pressure (active) air surfaces (one study with 72 participants; very low-certainty evidence).
- **Foam surfaces versus reactive fibre surfaces**. It is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between foam surfaces with reactive fibre surfaces (one study with 68 participants).
- **Foam surfaces versus reactive gel surfaces**. It is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between foam surfaces and reactive gel surfaces (one study with 135 participants).
- **Foam surfaces versus reactive foam and gel surfaces**. It is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between foam surfaces and reactive gel surfaces (one study with 91 participants).
- **Foam surfaces versus reactive water surfaces**. There are no analysable data for this comparison.
- **Foam surfaces versus another type of foam surface**. It is uncertain if there is a difference in the proportion of participants developing a new pressure ulcer between different types of foam surfaces (six studies with 733 participants). When we considered time to pressure ulcer incidence as our primary outcome, we found that viscoelastic foam surfaces with a density of 40 to 60 kg/m^3 may decrease the risk of developing incident pressure ulcers at time points up to 11.5 days' follow-up compared with foam surfaces with a density of 33 kg/m^3. Solid foam surfaces may also decrease the risk of developing incident pressure ulcers at time points up to one month's follow-up compared with convoluted foam surfaces. It is also uncertain if there is a difference in support-surface-associated patient comfort between different types of foam surface (four studies with 669 participants).

Overall completeness and applicability of evidence

As detailed in Search methods for identification of studies, we ran a comprehensive set of literature searches to maximise the relevant research included here.

Whilst use of foam surfaces is relevant to adults and children in any settings, all participants in the included studies were adults (with the reported average age ranging from 47 to 85.3 years, median of 76 years). Across the included studies, more than half (56.6%) of enrolled participants were female. Almost all of the studies enrolled people who were at (high) risk of pressure ulceration, with risk assessed using a risk assessment tool (e.g. the Braden scale), and who were ulcer-free at the time of recruitment. Four included studies (with 3089 participants) did include participants with superficial pressure ulcers at baseline. Most of the included studies were small (half had fewer than 100 participants), whilst eleven studies enrolled more than 200 participants, and seven studies more than 400. These seven trials together accounted for 71.6% (6853/9566) of the participants in the review.

The geographical scope of included studies was limited. Almost all the studies were from Europe and North America. One small study was from South Korea (Park 2017), and one small study was from Turkey (Ozyurek 2015).

The included studies recruited participants from a variety of care settings including: acute care settings (16 studies), community and long-term care settings (six studies), or both (two studies); intensive care units (three studies); and operating room (two studies). Whilst three of the seven comparisons included studies from a variety of care settings, due to a limited number of included studies for these three comparisons we could not perform pre-specified subgroup analysis by different care settings. Thus, for these comparisons, we are unable to drawn conclusions about potential modification of treatment effects in different care settings. The remaining four comparisons included data that were only from either acute care settings or nursing home settings and almost all of these four comparisons only included one study. Therefore, their evidence is very limited. These comparisons are foam surfaces compared with reactive water surfaces, reactive fibre surfaces, reactive gel surfaces, or reactive foam and gel surfaces. Additionally, the included data were limited for intensive care units and operating rooms.

We recognise that foam surfaces have evolved over decades and can have a range of features (e.g. foam density, foam thickness, layers of foam). The included studies were published from 1986 to 2018, and the specific foam surface types applied in the studies inevitably varied (see Appendix 4). In this review, we considered all specific foam types as foam surfaces because they have the same underlying mechanism of redistributing pressure activity (i.e. distributing the pressure over a greater area via immersion and envelopment).

We did not analyse data reported in the nine studies that compared foam surfaces with surfaces that we could not define using the NPIAP S3I 2007 support surfaces terms and definitions. However, for completeness of all relevant evidence, we reported the data of these studies in Appendix 5.

Another limitation in the included studies was the large variation in terms of follow-up durations (with a range from five days to 12 months, median of 14.5 days). This is partly because different follow-up durations are appropriate in different care settings. For example, participants staying at acute care settings are more likely to be discharged after a short-term hospital stay whilst those staying at community and

long-term care settings will typically stay for longer. The short median duration of follow-up may contribute to an under-estimation of pressure ulcer incidence across study groups of the included studies because most pressure ulcers would occur in the first two to four weeks after hospital admission (Schoonhoven 2007), and some incident pressure ulcers may have been missed in these studies.

Quality of the evidence

We implemented the GRADE approach for assessing the certainty of the evidence and found that most of the included evidence from our 15 meta-analyses or syntheses across seven comparisons was of low or very low certainty. Downgrading of evidence was largely due to the high risk of bias of findings, and imprecision due to small study sizes in terms of participants or event numbers, or both. There was also some inconsistency across studies for some comparisons.

Limitations in study design

We downgraded once or twice for study limitations for almost all evidence. We assessed risk of bias according to seven domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, selective outcome reporting, incomplete follow-up, and other potential biases. Of the 29 studies, we judged 17 as being at high overall risk of bias; and 12 at unclear overall risk of bias. The prevalence of high overall risk of bias is partly due to the non-blinding of participants and personnel for most comparisons. We acknowledged that such blinding of participants and personnel is impractical for most comparisons. Therefore, we did not downgrade certainty of evidence for studies at high overall risk of bias solely due to the possible presence of performance bias. Nine studies were also at high risk of bias due to unblinded outcome assessment. Unblinded assessment has been found to exaggerate odds ratios (from subjective binary outcomes) by, on average, 36% (Hróbjartsson 2012). The outcome assessment of pressure ulcer incidence is subjective and blinded assessment - whilst operationally challenging - can be undertaken (for example, through masked adjudication of photographs of pressure areas; Baumgarten 2009). Therefore, we considered unblinded pressure ulcer incidence assessment could substantially bias effect estimates in the included studies and downgraded the certainty of evidence for detection bias on a study-by-study basis.

Indirectness of evidence

We did not downgrade for all evidence. This was because we considered that the participants, interventions, and outcomes in the included studies were within the scope of the published review protocol and there was no indirectness.

Inconsistency of results and unexplained heterogeneity

Statistical heterogeneity was low for most of the evidence synthesis (11/15) we performed and we did not downgrade for inconsistency for these pieces of evidence. The low statistical heterogeneity was partly because eight of the 11 syntheses included only one study. We downgraded for inconsistency for the rest of the meta-analyses or narrative syntheses. None of these four analyses included more than six studies. Despite the fact that we found heterogeneity in terms of overall risk of bias, care settings, outcome measurement methods, or follow-up durations between the

included studies, we did not investigate their heterogeneity using subgroup analysis and we considered their heterogeneity (inconsistency) unexplained.

We have to note that although we had planned to calculate prediction intervals to understand the implications of heterogeneity, all analyses included a small number (up to seven) of included studies, which was fewer than the 10 needed for this calculation.

Imprecision of results

We downgraded once or twice for imprecision for 14 of 15 syntheses. Study sample sizes are small in most cases (median sample size: 101; range: 40 to 2029) with often small numbers of events and wide associated confidence intervals around effect estimates. Confidence intervals often crossed the line of null effect, thus meaning we could not discern whether the true population effect was likely to be beneficial or harmful.

Publication bias

We did not downgrade the certainty of evidence for publication bias in all meta-analyses. This is because (1) we have confidence in the comprehensiveness of our literature searches; and (2) we did not find any clear evidence of non-reporting bias of study results. Although we planned to perform funnel plots for meta-analysis to visually inspect for publication bias, there was no analysis including more than ten studies.

Potential biases in the review process

We followed pre-specified methods to review evidence in order to prevent potential bias in the review process. For example, we ran comprehensive electronic searches, searched trials registries, and checked references of systematic reviews identified in electronic searches.

This review also has limitations. Firstly, some included studies may have considered co-interventions as 'usual care' but did not fully describe them. We assumed that all studies had provided co-interventions equally to participants in their study groups if there was nothing to indicate that this was not the case. Secondly, we did not implement pre-specified subgroup analysis, as mentioned above, mainly because no analysis included more than 10 studies. Thirdly, we included a factorial design study in this review (Laurent 1998), but did not consider the potential interaction between interventions. Fourthly, only Nixon 2019 fully reported HRs and CIs related to time-to-event data. The HR and CI for Sauvage 2017 we used in Analysis 1.2 were calculated using the methods described in Tierney 2007; we recognised those calculated data (and associated meta-analyses) might be inaccurate. We noted that the time-to-event data analysis using the HR and CI we calculated tended to agree with the associated binary data analysis (Analysis 1.1) as we expected. Fifthly, eight studies described their controls as 'standard hospital surfaces' but did not specify construction materials of these surfaces. Although we made efforts to collect information on these surfaces, we were not able to classify them. Traditionally, ‘standard hospital surfaces' meant foam surfaces, but we felt adopting that assumption was unwarranted. Thus, we did not classify them as foam surfaces and we did not perform any analysis for the comparison of different types of foam surface. Finally, we were not able to pre-specify the comparisons included in this review. This

is because specific support surfaces applied could only be known and defined once eligible studies were included. However, we pre-planned to use the NPIAP S3I 2007 support surface terms and definitions to define specific support surfaces in order to avoid any potential bias.

Agreements and disagreements with other studies or reviews

To our knowledge, among the 14 systematic reviews or meta-analyses we identified in the electronic searches for this review (Chou 2013; Huang 2013; McGinnis 2011; McInnes 2015; McInnes 2018; Mistiaen 2010a; De Oliveira 2017; Rae 2018; Reddy 2006; Reddy 2008; Serraes 2018; Shi 2018a; Smith 2013; Yao 2018), two recent comprehensive reviews include foam surfaces evidence: Shi 2018a, and the Cochrane Review 'Support surfaces for pressure ulcer prevention' (McInnes 2015).

This review differs from Shi 2018a and McInnes 2015 in how specific support surfaces (including foam surfaces) are classified and labelled. As mentioned above, the types of foam surface used in the included studies varied, and we labelled all these types as 'foam surfaces'. However, Shi 2018a and McInnes 2015 used the term 'high specification foam' surfaces. Whilst this term is used in pressure ulcer guidelines and there is an Australian consensus on characteristics that constitute a high specification foam mattress (e.g. foam density, thickness), it has been deprecated by the NPIAP S3I. NPIAP S3I 2007 noted that the term 'high specification foam surfaces' "potentially limits clinical options because it is based on materials not system performance characteristics". Additionally, the characteristics of foam surfaces used in the included studies were not always given (see Appendix 4). Some studies specified the foam density of foam surfaces whilst others only specified thickness and foam materials (e.g. viscoelastic foam, or polyurethane foam). It is inappropriate to group all specific foam surfaces across studies as high specification foam surfaces.

In terms of the included comparators, Shi 2018a considered reactive air-fluidised surfaces, reactive air surfaces and reactive low-air-loss surfaces as separate groups whilst we considered them a single generic group, 'reactive air surfaces'. Likewise, Shi 2018a considered alternating pressure (active) low-air-loss surfaces, alternating pressure (active) air surfaces, and hybrid air surfaces as separate groups whilst we considered them a single generic group, 'alternating pressure (active) air surfaces'.

Shi 2018a grouped some interventions under the term 'standard hospital surfaces' but concluded that the types of surfaces labelled in this way varied over time, and by setting. McInnes 2015 applied the terms 'standard hospital foam' and 'standard hospital mattresses' in one specific comparison. We noted that the NPIAP S3I 2007 recommends that the term 'standard hospital surfaces' should be avoided for use and the surface characteristics should be specified. In this review, we made great efforts to define surfaces where these surfaces were described as a 'standard hospital surface' in the included studies to ensure they were placed in the correct comparisons. We classified 'standard hospital surfaces' that had no characteristic details or could not fit the NPIAP S3I 2007 support surfaces terms and definitions as undefined surfaces.

These above re-definitions and re-classifications of specific support surfaces can explain some of the inconsistency between these reviews, but importantly, Shi 2018a was a network meta-analysis.

Shi 2018a considered pressure ulcer incidence and support-surface-associated patient comfort outcomes only whilst this review adds cost-effectiveness evidence to the evidence base and suggests that alternating pressure (active) air surfaces are probably more cost-effective than foam surfaces.

Shi 2018a indicated an evidence gap around the comparison of foam surfaces versus alternating pressure (active) air surfaces, and expected to tackle this gap by including a large, then ongoing study - Nixon 2019 - in data analysis. This review did include this study, but this inclusion still resulted in some uncertain evidence with the use of pairwise meta-analysis methods. Further planned review work using network meta-analysis will add to the findings reported here.

McInnes 2015 suggested that the so-called 'high specification foam mattress' can reduce pressure ulcer incidence compared with standard hospital surfaces. We did not perform any analysis for the comparison of foam surfaces versus 'standard hospital surfaces'.

Authors' conclusions

Implications for practice

The current evidence base is full of uncertainties about the difference in pressure ulcer incidence between using foam surfaces and some other surfaces (i.e. reactive fibre surfaces, reactive gel surfaces, reactive foam and gel surfaces, or reactive water surfaces). Foam surfaces may increase the risk of pressure ulcer development in comparisons with alternating pressure (active) air surfaces and with reactive air surfaces. Alternating pressure (active) air surfaces are probably more cost-effective than foam surfaces. When considering different types of foam surface, viscoelastic foam surfaces with a density of 40 to 60 kg/m^3 may reduce the risk of developing incident ulcers over 11.5 days' follow-up compared with foam surfaces with a density of 33 kg/m^3 in people treated in the intensive care unit setting. Solid foam surfaces may also reduce the risk of developing pressure ulcers over one month's follow-up compared with convoluted foam surfaces in people treated in acute care and long-term care settings.

Implications for research

Given the large number of different support surfaces available, future studies should prioritise which support surfaces to evaluate on the basis of the priorities of decision-makers. For example, foam surfaces versus reactive gel surfaces may be a high priority for future evaluation, particularly in operating rooms. All interventions used should be clearly described using the current classification system. Researchers should avoid the use of some terms such as 'high specification foam surfaces' and 'standard hospital surfaces' without further detail about the specific nature of the support surfaces being evaluated. Limitations in included studies are largely due to small sample size and sub-optimal RCT design. The incidence of pressure ulcers can be low in certain settings and this needs to be considered in sample size calculations and when considering the feasibility of trial conduct. Under-recruitment or over-estimation of event rates that then fail to occur, or both, can lead to imprecision and less robust effect estimates.

Future studies should also consider carefully the choice of outcomes they report. Time-to-event data for pressure ulcer incidence should be used in studies. Careful and consistent assessment and reporting of adverse events needs to be undertaken to generate

meaningful data that can be compared between studies. Likewise, patient comfort is an important outcome but poorly defined and reported, and this needs to be considered in future research studies. Further studies should aim to collect and report health-related quality of life using validated measures. Finally, future studies should nest cost-effectiveness analysis in their conduct where possible.

Any future studies must be undertaken to the highest standard possible. Whilst it is challenging to avoid the risk of performance bias in trials of support surfaces as blinding of participants and personnel is seldom possible, stringent protocols - for example, in terms of encouraging consistent care and blinded decision-making - can help to minimise risk. It is also important to fully describe co-interventions (e.g. repositioning) and ensure protocols mandate balanced use of these across trial arms. The risk of detection bias can also be minimised with the use of digital photography and adjudicators of the photographs being masked to support surfaces (Baumgarten 2009). Follow-up periods should be for as long as possible and clinically relevant in different settings. Where possible and useful, data collection after discharge from acute settings may be considered.

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Data and analyses

Comparison 1

Foam surfaces compared with alternating pressure (active) air surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size	
1.1 Proportion of participants developing a new pressure ulcer	4	2247	Risk Ratio (M-H, Random, 95% CI)	1.59 [0.86, 2.95]	
1.2 Time-to-pressure ulcer incidence	2		Hazard Ratio (IV, Random, 95% CI)	2.46 [0.61, 9.88]	

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size	
1.3 Health-related quality of life	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only	
1.3.1 90-day EQ-5D-5L	1	267	Mean Difference (IV, Fixed, 95% CI)	0.00 [-0.05, 0.05]	
1.3.2 90-day PU-QoL-UI	1	233	Mean Difference (IV, Fixed, 95% CI)	0.00 [-0.03, 0.03]	

Comparison 2

Foam surfaces compared with reactive air surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size	
2.1 Proportion of participants developing a new pressure ulcer	4	229	Risk Ratio (M-H, Random, 95% CI)	2.40 [1.04, 5.54]	

Comparison 3

Foam surfaces compared with reactive fibre surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size	
3.1 Proportion of participants developing a new pressure ulcer	1	68	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.64, 2.14]	

History

Protocol first published: Issue 5, 2020
Review first published: Issue 4, 2021

Contributions of authors

Chunhu Shi: conceived the review; designed the review; coordinated the review; extracted data; analysed or interpreted data; undertook quality assessment; performed statistical analysis; produced the first draft of the review; contributed to writing or editing the review; wrote to study authors/experts/companies; approved the final review prior to publication; is guarantor of the review.

Jo Dumville: conceived the review; designed the review; coordinated the review; analysed or interpreted data; checked quality of statistical analysis; produced the first draft of the review; contributed to writing or editing the review; advised on the review; secured funding; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Nicky Cullum: conceived the review; designed the review; coordinated the review; checked quality of data extraction; contributed to writing or editing the review; advised on the review; secured funding; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Sarah Rhodes: conceived the review; designed the review; checked quality of data extraction; checked quality assessment; checked quality of statistical analysis; contributed to writing or editing the review; advised on the review; approved the final review prior to publication.

Elizabeth McInnes: conceived the review; designed the review; coordinated the review; checked quality of data extraction; checked quality assessment; contributed to writing or editing the review; advised on the review; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Contributions of the editorial base

Gill Norman (Editor): edited the protocol; advised on methodology, interpretation and content; approved the final protocol prior to publication.

Gill Rizzello (Managing Editor): coordinated the editorial process; advised on content; edited the protocol and the review.

Sophie Bishop (Information Specialist): designed the search strategy and edited the search methods section.

Tom Patterson (Editorial Assistant): edited the reference sections of the protocol and the review.

Declarations of interest

Chunhu Shi: I received research funding from the National Institute for Health Research (Research for Patient Benefit, Evidence synthesis for pressure ulcer prevention and treatment, PB-PG-1217-20006). I received support from the Tissue Viability Society to attend conferences unrelated to this work. The Doctoral Scholar Awards Scholarship and Doctoral Academy Conference Support Fund (University of Manchester) also supported a PhD and conference attendance respectively, both were unrelated to this work.

Jo Dumville: I am Chief Investigator on a National Institute for Health Research grant that funded the conduct of this review (Research for Patient Benefit, Evidence synthesis for pressure ulcer prevention and treatment, PB-PG-1217-20006). This research was co-funded by the National Institute for Health Research Manchester Biomedical Research Centre and partly funded by the National Institute for Health Research Applied Research Collaboration, Greater Manchester.

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- National Institute for Health Research (NIHR), UK

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Differences between protocol and review

- Two review authors independently assessed the titles and abstracts of the new search results for relevance using Rayyan rather than using Covidence.
- For new included studies, one review author independently extracted data and another review author checked all data, rather than two review authors independently carrying out data extraction.
- When a study only had complete case data, we considered complete case data in the related main analysis (i.e. assuming no missing data issue). This was not pre-planned.
- We presented separate 'Summary of findings' tables for five of the seven comparisons evaluated in this review. We did not present the tables for the comparison between different types of foam surfaces and the comparison of foam surfaces versus reactive water surfaces.
- Where we did not pool data, we conducted a GRADE assessment and presented these assessments in a narrative format in 'Summary of findings' tables. This was not pre-planned.

Characteristics of studies

Characteristics of included studies [ordered by study ID]

Allman 1987

Study characteristics	
Methods	**Study objective**: to compare the effectiveness and adverse effects of air-fluidised beds and conventional therapy for patients with pressure sores **Study design including the number of centres**: randomised controlled trial, single centre **Study grouping**: parallel group **Duration of follow-up**: median 13 days **Number of arms**: 2

	Study start date and end date: recruited between October 1984 and March 1986 **Care setting**: urban, academic referral, and primary care medical centre
Participants	**Baseline characteristics** **Inclusion criteria**: age greater than 18 years old; presence of a pressure sore on the sacrum, buttocks, trochanters or back; activity expected to be limited to bed or chair in the hospital for at least 1 week; patient expected to live at least 1 week; informed consent obtained **Exclusion criteria**: had been in the trial previously or a skin graft or flap planned for the pressure sore within 1 week **Sex (M/F)**: 27/38 overall. 11/20 in air-fluidised bed; 16/18 in conventional therapy **Age (years)**: mean 65.5 (SD 15.6) in air-fluidised bed, 67.6 (18.3) in conventional therapy **The stage of pressure ulcers at baseline**: 16 superficial and 15 deep ulcers on air-fluidised bed; 20 superficial and 14 deep ulcers on conventional therapy. Median total surface area 7.8 cm^2 (range 0.3 to 83.2) on air-fluidised bed, 10.8 (0.4 to 180.3) on conventional therapy **Group difference**: no difference **Total number of participants**: 72 patients (65 completed the study) **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Air-fluidised bed • **Description of interventions:** air-fluidised bed (Clinitron Therapy, Support Systems International, Inc.)… contain ceramic beads … warm, pressurised air is forced up through the beads, on the characteristics of a fluid • **NPIAP S3I classification:** non-powered, reactive air-fluidised surface • **Number of participants randomised:** not given • **Number of participants analysed:** 31 • **Co-interventions:** repositioning every 4 hours without use of other anti-pressure devices Conventional therapy • **Description of interventions:** used a vinyl alternating air-mattress covered by a 19 mm thick foam pad (Lapidus Air Float System, American Pharmaceal Company) on a regular bed • **NPIAP S3I classification:** non-powered, reactive foam surface plus powered, alternating pressure (active) air surface • **Number of participants randomised:** not given • **Number of participants analysed:** 34 • **Co-interventions:** repositioning every 2 hours and elbow or heel pads as needed
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: median 13 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: skin breakdown or epidermal necrosis manifested by eschar over a bony prominence; defined by Shea system; not staged

- **Definition (including ulcer stage)**: new skin breakdown
- **Dropouts**: 7 withdrew prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed)
- **Notes (e.g. other results reported)**: 9 of 31 on air-fluidised beds vs 15 of 34 on conventional therapy (P = 0.24)

Time to pressure ulcer incidence

- **Reporting:** not reported

Support-surface-associated patient comfort

- **Outcome type**: categorical
- **Time points**: median 13 days
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: patients with change in comfort from baseline. Level of comfort assessed by asking the patient to respond to a second question scored from 1 to 4: "Which of the following best describes the bed you are using here in the hospital: very comfortable, comfortable, uncomfortable, or very uncomfortable?"
- **Dropouts and reasons**: 7 withdrew prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed)
- **Data and results**: 8 comfort increased, 4 no change and 1 decreased on air-fluidised bed; 3 increased, 4 no change and 6 decreased on conventional therapy (P = 0.04)
- **Notes (e.g. other results reported)**:

All reported adverse events

- **Outcome type**: binary
- **Time points**: median 13 days
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: patients developing complications
- **Dropouts and reasons**: 7 withdrew prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed)
- **Data and results**: 8 died, 2 pneumonia, 10 urinary tract infections, 6 hypotension, 5 hypernatraemia, 5 oliguria, 7 sepsis, 16 fever, and 3 heart failure on air-fluidised bed; 7 died, 4 pneumonia, 7 urinary tract infections, 7 hypotension, 5 hypernatraemia, 8 oliguria, 6 sepsis, 22 fever, and 6 heart failure on conventional therapy
- **Notes (e.g. other results reported)**: some patients appeared to have multiple adverse events

Health-related quality of life (HRQOL)

- **Not reported**

Cost-effectiveness

- **Not reported**

Outcomes that are not considered in this review but reported in trials:

- Ulcer healing
- Change in total surface area
- Patients improved

	• 50% reduction in total surface area • Pain response
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly allocated to treatment groups in two strata in balanced blocks of six with stratification … The randomization sequence was determined using a table of random numbers …" Comment: low risk of bias due to the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Quote: "… treatment allocations were placed in envelopes sealed and numbered sequentially. After establishing eligibility, one of the investigators selected the unopened envelope with the lowest number in the appropriate strata and allocated the patient to the treatment indicated on the enclosed card" Comment: unclear risk of bias because it is unclear if the envelopes are opaque.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: ulcer incidence*** Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes*** Comment: low risk of bias because of the low rate of attrition (7/72, 9.7%).
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Berthe 2007

Study characteristics	
Methods	**Study objective**: to determine the effectiveness in pressure-sore prevention of an interface pressure-decreasing mattress, the Kliniplot® mattress **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 7 months **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described; recruited between October 1997 and April 1998 **Setting**: hospital
Participants	**Baseline characteristics** **Inclusion criteria**: patients free of bed-sores admitted for at least 24 hours to 3 medical and 3 surgical departments

	Exclusion criteria: patients with disc hernias in the department of neurosurgery; and those with pressure sores **Sex (M:F)**: not given **Age (years)**: not given **Baseline skin status**: overall mean modified Ek's scale score 3.56 (SD 0.84) estimated by the review authors using the reported raw data; without existing ulcers **Group difference**: no difference in baseline pressure ulcer risk **Total number of participants**: n = 1729 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Kliniplot® mattress • **Description of interventions**: mattress with a foamy-block structure. The mossy blocks were designed to decrease the localised high interface pressure points, by redistributing the pressure along the entire surface of the patient. • **NPIAP S3I classification:** non-powered, reactive foam surface; the foam characteristics unspecified • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 657 Standard hospital mattress • **Description of interventions**: standard mattress • **NPIAP S3I classification**: standard hospital surface • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 1072
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 7 months • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: graded the severity of pressure sores by using the modified Shea's pressure sore grading • **Definition (including ulcer stage)**: incidence of ulcers at any stage • **Dropouts**: not described • **Notes (e.g. other results reported)**: 21 of 657 patients (3.2%) on Kliniplot® mattress, and 21 of 1072 patients (1.9%) on standard mattress developed bed-sores (P = 0.154) *Time to pressure ulcer incidence* • **Outcome type**: time-to-event (but not survival analysis) • **Time points**: 7 months • **Reporting:** fully reported • **Measurement method (e.g. scale, self-reporting)**: see above • **Definition (including ulcer stage)**: median time to pressure ulcer

	incidence • **Dropouts**: not given • **Notes**: median time to pressure ulcer incidence 31 days (range 6 to 87) for Kliniplot® mattress and 18 days (range 2 to 38) for standard mattress (P < 0.001). HR 0.35 (95% CI 0.19 to 0.66) estimated by the review authors by using methods described in Tierney 2007. *Support-surface-associated patient comfort* • **Not reported** *All reported adverse events using allocated support surfaces* • **Not reported** *Health-related quality of life (HRQOL)* • **Not reported** *Cost-effectiveness* • **Not reported** **Outcomes that are not considered in this review but reported in trials**: • None
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... were freely assigned to a bed which has been randomly equipped in advance either with a Kliniplot® mattress, or with a standard mattress" Comment: unclear risk of bias because the sequence generation method is not specified.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: no information provided.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Bliss 1995a

Study characteristics

Methods	**Study objective**: to identify inexpensive and, if possible, non-mechanical constant low pressure overlays effective for patients at long-term risk in continuing-care wards for elderly people **Study design**: randomised controlled trial (a poorly designed multi-arm multi-stage trial, with re-randomisation) **Study grouping**: parallel group **Duration of follow-up**: not given; assessment with a mean of 17.7 days **Number of arms**: 7 (the trial had a Vaperm as control arm but its participants were not randomised. Vaperm data were not extracted for this review) **Single centre or multi-sites**: not specified **Study start date and end date**: not described **Setting**: hospital
Participants	**Baseline characteristics** **Inclusion criteria**: patients liable to pressure sores; including those who already had superficial breaks in the skin of the pressure areas **Exclusion criteria**: patients with superficial sores > 5 cm and discoloured areas > 2 cm diameter **Sex (M:F)**: overall 62:296 (treatment sessions rather than individuals) **Age (years)**: mean 84.4 (range 67 to 97) large cell Ripple bed (n = 71 treatment sessions of 34 patients); 85.2 (67 to 97) Preventix (n = 25 sessions of 20 patients); 85.6 (68 to 98) Groove (n = 66 sessions of 36 patients); 86.1 (68 to 98) Modular Propad (n = 60 sessions of 39 patients); 84.4 (68 to 93) Ardo Watersoft (n = 32 sessions of 22 patients); 85.6 (68 to 94) Spenco (n = 63 sessions of 35 patients); 84.3 (67 to 97) Surgicgoods Hollowcore (n = 41 sessions of 30 patients) **Baseline skin status**: not given; those with superficial ulcers included **Group difference**: not given **Total number of participants**: n = 358 sessions of 216 patients **Unit of analysis**: treatment sessions of patients **Unit of randomisation (per patient)**: treatment sessions of patients
Interventions	**Intervention characteristics** Groove • **Description of interventions**: a contoured 10-centimetre thick foam overlay • **NPIAP S3I classification:** non-powered, reactive foam surface; lack of information for specifying foam characteristics • **Co-interventions**: not described • **Number of participants randomised**: n = 66 sessions of 36 patients • **Number of participants analysed**: n = 66 sessions of 36 patients Spenco • **Description of interventions**: one-piece cotton hollow-core fibrefill • **NPIAP S3I classification:** non-powered, reactive fibre surface • **Co-interventions**: not described • **Number of participants randomised**: n = 63 sessions of 35 patients • **Number of participants analysed**: n = 63 sessions of 35 patients Propad • **Description of interventions**: Modular Propad was an 8.5-centimetre thick foam pad with the upper surface moulded into air-ducted, rounded horizontal blocks • **NPIAP S3I classification:** non-powered, reactive foam surface; lack of

	information for specifying foam characteristics • **Co-interventions**: not described • **Number of participants randomised**: n = 60 sessions of 39 patients • **Number of participants analysed**: n = 60 sessions of 39 patients Preventix • **Description of interventions**: a 16-centimetre thick mat of 8-centimetre square foam modules of different densities inserted into a flexible PVC frame ... providing a variably soft, contoured, slit surface to optimise pressure distribution • **NPIAP S3I classification:** non-powered, reactive foam surface; lack of information for specifying foam characteristics • **Co-interventions**: not described • **Number of participants randomised**: n = 25 sessions of 20 patients • **Number of participants analysed**: n = 25 sessions of 20 patients Surgicgoods • **Description of interventions**: Surgicgoods Hollowcore Mattress pad was a one-piece fibrefill • **NPIAP S3I classification:** non-powered, reactive fibre-filled surface • **Co-interventions**: not described • **Number of participants randomised**: n = 41 sessions of 30 patients • **Number of participants analysed**: n = 41 sessions of 30 patients Watersoft • **Description of interventions**: Ardo Watersoft consisting of three 4-centimetre deep, partly-filled water cushions with stabilising baffles • **NPIAP S3I classification:** non-powered, reactive water-filled surface • **Co-interventions**: not described • **Number of participants randomised**: n = 32 sessions of 22 patients • **Number of participants analysed**: n = 39 sessions of 22 patients Large cell Ripple bed • **Description of interventions**: consisting of 14 horizontal cells 10 cm in diameter in the centre, connected in 2 alternating series, powered by a small pump which caused them to inflate and deflated reciprocally underneath the patient every 10 minutes, thus continually changing the supporting points of pressure • **NPIAP S3I classification:** powered, alternating pressure (active) air surface • **Co-interventions**: not described • **Number of participants randomised**: n = 71 sessions of 34 patients • **Number of participants analysed**: n = 71 sessions of 34 patients
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Not reported** • **Notes (e.g. other results reported)**: numbers of trials in which sores developed or worsened: 11 of 71 Ripple bed; 9 of 25 Preventix; 27 of 66 Groove; 26 of 60 Propad; 19 of 32 Watersoft; 38 of 63 Spenco; 26 of 41 Surgicgoods *Time to pressure ulcer incidence* • **Not reported**

	Support-surface-associated patient comfort • **Not reported** *All reported adverse events using allocated support surfaces* • **Not reported** *Health-related quality of life (HRQOL)* • **Not reported** *Cost-effectiveness* • **Not reported** **Outcomes that are not considered in this review but reported in trials**: • None
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "the patient was randomly allocated to an experimental overlay by the researcher writing the names of all those available at the time on slips of paper which were folded and offered to the nurse to choose one blind" Comment: low risk of bias because drawing of lots is applied to generate random sequence.
Allocation concealment (selection bias)	High risk	Quote: "the patient was randomly allocated to an experimental overlay by the researcher writing the names of all those available at the time on slips of paper which were folded and offered to the nurse to choose one blind. The designated overlay was then placed on the bed" Comment: high risk of bias because it appears difficult to conceal the allocation process as the authors described. The nurse would have knowledge of which overlays were available at the time of consent.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: no information provided.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	High risk	Comment: high risk of bias because some individuals may be repeatedly observed and included in analysis (i.e. correlation issue in analysis). For example, Bliss stated "there were no written criteria determining the decision to stop a trial [i.e. using an overlay as the experimental intervention]. This depended mainly on these experienced nurses' unwillingness to allow it to continue because of enlargement of an existing sore, a new blister, discolouration, oedema ... Patients who developed pressure damage between assessments might also be taken

		off their overlay ... if they later improved ... they were re-randomized for another trial period [i.e. comparisons of new overlays]." Additionally, overlays were observed for unequally periods of time. Treatments were discontinued or introduced without prespecified stopping rules. Some comparisons are not parallel.

Bueno de Camargo 2018

Study characteristics	
Methods	**Study objective:** to analyse whether a viscoelastic mattress support surface can reduce the incidence of stage 2 pressure injuries compared to a standard hospital mattress with pyramidal overlay in critically ill patients **Study design:** randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: not described; followed until intensive care unit (ICU) discharge; median length of ICU stay 11.5 days (interquartile range (IQR) 7.5 to 22) **Number of arms: 2** **Single centre or multi-sites:** single centre **Study start date and end date**: 2016 to 2017 **Setting:** ICU
Participants	**Baseline characteristics** **Inclusion criteria**: critically ill patients at moderate or higher risk for development of pressure injuries; that is, those presenting a Braden ≤ 14 scale (moderate, high or very high risk) at ICU admission **Exclusion criteria:** age less than 18 years, length of stay in the ICU for less than 24 hours, contraindication for the performance of the standard pressure injuries prevention measures of the institution, presence of pressure injuries at ICU admission, and absence of the informed consent form **Sex (M:F)**: 33:29 overall **Age (years)**: mean 67.9 (SD 18.8) overall; 71.5 (18.0) in pyramidal overlay; 64.2 (19.2) in viscoelastic foam **Baseline skin status**: mean Braden score 10.8 (SD 1.7) overall; all at risk but no existing ulcers **Group difference:** not described **Total number of participants:** n = 62 **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Viscoelastic mattress • **Description of interventions**: Viscoelastic foam is a type of porous polymer material that conforms in proportion to the applied weight ... used a viscoelastic mattress as a bedding surface with the following characteristics: 5-centimetre layer of cold foam with a density of 40, and 7-centimetre layer of viscoelastic foam with a density of 60 (Sweet Pedic Hospitalar®) measuring 190 by 90 centimetres • **NPIAP S3I classification:** non-powered, reactive foam surface; high specification (viscoelastic) foam (density of 40 and 60) • **Co-interventions**: institution's pressure injuries prevention measures • **Number of participants randomised**: n = 31 • **Number of participants analysed**: n = 31

	Standard mattress with pyramidal overlay • **Description of interventions**: used a standard hospital mattress covered with a pyramidal overlay. The standard hospital mattress is a 12-centimetre cold foam with a density of 33 measuring 188 by 80 centimetres. The pyramidal overlay is a 5-centimetre layer of polyurethane foam, density 33, whose surface looks like egg carton. • **NPIAP S3I classification:** non-powered, reactive foam surface; foam (density of 33) • **Co-interventions**: institution's pressure injuries prevention measures • **Number of participants randomised**: n = 31 • **Number of participants analysed**: n = 31

Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: on average of 30 days (NCT02844166) • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not described; the definition appears to be equivalent to NPUAP system • **Definition (including ulcer stage)**: incidence of stage 2 pressure injuries: partial-thickness loss of skin with exposed dermis • **Dropouts**: intention-to-treat (ITT) analysis • **Notes (e.g. other results reported)**: ulcers occurred in 35 patients; higher in pyramidal overlay (25 of 31; 80.6%) compared to viscoelastic foam mattress (10 of 31; 32.2%) P < 0.001 *Time to pressure ulcer incidence* • **Outcome type**: time-to-event • **Time points**: on average 30 days (NCT02844166) • **Reporting:** fully reported • **Measurement method (e.g. scale, self-reporting)**: not described • **Definition (including ulcer stage)**: time from intensive care unit admission to identification of class II pressure injury • **Dropouts**: median time to develop an ulcer 8.5 days (interquartile range (IQR) 5.0 to 14.0) in viscoelastic mattress; 6.0 days (IQR 3.0 to 8.0) in pyramidal overlay; Mann-Whitney test P = 0.088; Kaplan–Meier curve presented in Figure 2. HR 0.33 (95% CI 0.17 to 0.64), estimated by the review authors using the methods described in Tierney 2007. *Support-surface-associated patient comfort* • **Reporting:** not reported *All reported adverse events using allocated support surfaces* • **Reporting:** not reported *Health-related quality of life (HRQOL)* • **Reporting:** not reported *Cost-effectiveness* • **Reporting:** not reported **Outcomes that are not considered in this review but reported in trials:** • Mortality rate (mentioned in NCT02844166 but not reported in the study's paper).
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was performed using a computerized table, and patients were allocated into two groups" Comment: low risk of bias because a proper randomisation method used.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.

Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: pressure ulcer incidence*** Quote: "the blinding of the health team was not possible" Comment: high risk of bias as the authors stated no blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: pressure ulcer incidence*** Quote: "the blinding of the health team was not possible" Comment: high risk of bias as the authors stated no blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: pressure ulcer incidence*** Comment: low risk of bias because the paper clearly states ITT analysis performed.
Selective reporting (reporting bias)	High risk	Comment: high risk of bias because even though the study protocol is available but it is clear that the published report does not include mortality outcome that was pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Collier 1996

Study characteristics	
Methods	**Study objective**: to compare 8 new foam mattresses with a new standard 180 mm hospital mattress, and to define their ability to reduce the incidence of pressure sore formation and to provide comfort **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: not described **Number of arms**: 8 (7 of them were combined into 1 arm) **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: not described **Exclusion criteria**: not described **Sex (M:F)**: overall 40:59 **Age (years)**: not described **Baseline skin status**: all patients were included irrelevant of Waterlow Score **Group difference**: not described **Total number of participants**: not described **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Clinifloat • **Description of interventions**: Clinifloat (SSI Medical Services Ltd) • **NPIAP S3I classification:** non-powered, reactive foam surface; insufficient information for specifying foam quality • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 11

Omnifoam

- **Description of interventions**: Omnifoam (HNE Healthcare). Extra information from Santy 1994: "Omnifoam (Huntleigh Nesbit Evans Healthcare) made of a high quality multilayer foam construction, ventilated high density foam"
- **NPIAP S3I classification:** non-powered, reactive foam surface; high-specification
- **Co-interventions**: not described
- **Number of participants randomised**: not described
- **Number of participants analysed**: n = 11

Softform

- **Description of interventions**: Softform (Medical Support System)
- **NPIAP S3I classification:** non-powered, reactive foam surface; high-specification according to Gray 1994
- **Co-interventions**: not described
- **Number of participants randomised**: not described
- **Number of participants analysed**: n = 12

STM5

- **Description of interventions**: STM5 (Servies to Medicine)
- **NPIAP S3I classification:** non-powered, reactive foam surface; insufficient information for specifying foam quality
- **Co-interventions**: not described
- **Number of participants randomised**: not described
- **Number of participants analysed**: n = 10

Therarest

- **Description of interventions**: Therarest (KCI Medical Ltd)
- **NPIAP S3I classification:** non-powered, reactive foam surface; insufficient information for specifying foam quality
- **Co-interventions**: not described
- **Number of participants randomised**: not described
- **Number of participants analysed**: n = 13

Transfoam

- **Description of interventions**: Transfoam (Karomed)
- **NPIAP S3I classification:** non-powered, reactive foam surface; high-specification according to Gray 2000
- **Co-interventions**: not described
- **Number of participants randomised**: not described
- **Number of participants analysed**: n = 10

Vapourlux

- **Description of interventions**: Vapourlux (Parkhouse)
- **NPIAP S3I classification:** non-powered, reactive foam surface; insufficient information for specifying foam quality
- **Co-interventions**: not described
- **Number of participants randomised**: not described
- **Number of participants analysed**: n = 14

	NHS standard contract 130 mm foam mattress • **Description of interventions**: NHS standard contract 130 mm foam mattress (Manufacturer: Reylon Ltd) • **NPIAP S3I classification:** non-powered, reactive foam surface; insufficient information for specifying foam quality • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 9
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not described • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not described • **Definition**: "Deterioration of skin condition as a result of the effects of pressure" reported is deemed to cover the condition of pressure ulcer • **Dropouts**: not described • **Notes**: no deterioration of skin condition across groups *Time to pressure ulcer incidence* • **Reporting:** not reported *Support-surface-associated patient comfort* • **Outcome type**: • **Time points**: not described • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: assessed using a standardised question and visual rating scale (1 = poor, 10 = excellent) • **Definition**: not described • **Dropouts**: not described • **Notes**: range of patient comfort assessments 5 to 7 in Clinifloat (n = 11); 0 to 0 in NHS Standard (n = 9); 3 to 8 in Omnifoam (n = 11); 8 to 11 in Softform (n = 12); 9 to 9 in STM5 (n = 10); 8 to 8 in Therarest (n = 13); 2 to 8 in Transfoam (n = 10); 10 to 10 in Vapourlux (n = 14) *All reported adverse events using allocated support surfaces* • **Reporting:** not reported *Health-related quality of life (HRQOL)* • **Reporting:** not reported *Cost-effectiveness* • **Reporting:** not reported **Outcomes that are not considered in this review but reported in trials**: • No
Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Unclear risk	Quote: "Mattresses were randomly allocated to patients on admission as available" Comment: unclear if a proper randomisation method was applied.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Quote: "The mattresses were coded numerically ... with their identification number clearly displayed above the bed ... To reduce bias, ... only the principal investigator and the ward link nurse knew the identification of each mattress" Comment: unclear risk of bias for both pressure ulcer and comfort outcomes because it is unclear if these foam mattresses are similar to each other and if investigator and the link nurse are involved in patient care.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: all outcomes*** Quote: "Patients were periodically reassessed ... and any evidence of skin deterioration was documented ... conducted at least weekly throughout their period in hospital" Comment: high risk of bias for both pressure ulcer and comfort outcomes because it is unlikely that blinding was implemented for participants and personnel given the information provided. Self-reported comfort outcome cannot be measured in a blinded way.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes*** Comment: no attrition identified.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Feuchtinger 2006

Study characteristics	
Methods	**Study objective**: to assess the effect of a 4 cm thermoactive viscoelastic foam overlay with a water-filled warming mattress on the operating room-table compared with the standard operating room-table (a water-filled warming mattress, no pressure-reducing device) on the postoperative pressure ulcer incidence in cardiac surgery patients. **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 5 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: January to June 2004 **Setting**: Department for Cardiovascular Surgery of a university hospital
Participants	**Baseline characteristics** **Inclusion criteria**: scheduled for cardiac surgery with extracorporal circulation, aged ≥ 18 years, not included in another study, and written informed consent obtained **Exclusion criteria**: not described

	Sex (M:F): 58: 27 in test table; 67: 23 in standard table **Age (years)**: mean 68 (SD 11) in test table; 67.6 (10.8) in standard table **Baseline skin status**: mean Norton score 22.6 (SD 1.9) in test table; 22.2 (2.4) in standard table **Group difference**: no difference **Total number of participants**: n = 175 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Test operating room table • **Description of interventions**: a 4 cm thermoactive viscoelastic foam pad combined with a warming mattress on the operating table • **NPIAP S3I classification:** non-powered, reactive foam surface; 4 cm viscoelastic foam operating table pad • **Co-interventions**: not described • **Number of participants randomised**: n = 85 • **Number of participants analysed**: n = 85 Standard operating room table • **Description of interventions**: a warming mattress on the operating table, no pressure-reducing device • **NPIAP S3I classification**: standard hospital surface; standard operating table • **Co-interventions**: not described • **Number of participants randomised**: n = 90 • **Number of participants analysed**: n = 90
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: post-operative 5 days • **Reporting:** fully reported • **Measurement method (e.g. scale, self-reporting)**: measured by nurses using the EPUAP 2005 classification system • **Definition (including ulcer stage)**: postoperative pressure ulcer incidence of any grade • **Dropouts**: intention-to-treat (ITT) analysis • **Notes (e.g. other results reported)**: 15 of 85 individuals (17.6%) in test table group (including 13 Grade 1 and 2 Grade 2); 10 of 90 (11.1%) standard table group (including 9 Grade 1 and 1 Grade 2) *Time to pressure ulcer incidence* • **Outcome type**: time-to-event • **Time points**: 5 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: see above • **Definition (including ulcer stage)**: see above • **Dropouts**: ITT analysis • **Notes**: these data were read by review authors based on raw incidence data and days: 11 in day 0, 3 in day 1, 1 in day 3, and 0 in day 5 in test

	table group; 7 in day 0, 1 in day 1, 2 in day 3, and 0 in day 5 in standard table group. lnHR 0.48, selnHR 0.66 estimated by the review authors by using methods described in Tierney 2007. *Support-surface-associated patient comfort* • **Reporting:** not reported *All reported adverse events using allocated support surfaces* • **Reporting:** not reported *Health-related quality of life (HRQOL)* • **Reporting:** not reported *Cost-effectiveness* • **Reporting:** not reported **Outcomes that are not considered in this review but reported in trials:** • No
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Included patients were randomised to either the standard operating table configuration or the test configuration" Comment: the method of randomisation was not reported.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "Patients were also kept unaware of the configuration [experimental intervention]" Comment: unclear risk of bias because it is unclear if personnel were blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: primary outcome*** Quote: "The postoperative nurses who assessed the skin condition were unaware of the patient assignment." Comment: low risk of bias because pressure ulcer incidence outcome assessment was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: primary outcome*** Quote: "Missing values were substituted in concordance with baseline carry forward principle. Statistical analysis was based on the intention to treat principle" Comment: low risk of bias because ITT analysis was conducted.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Gray 1994

Study characteristics

Methods	**Study objective**: to fully evaluate and define the clinical abilities of the standard 130 mm contract mattress and the Softform mattress in regards to their ability to provide the patient with adequate pressure reduction, so as to prevent pressure sore formation, and provide the patient with adequate comfort. **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 10 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: acute care settings of a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: patients from orthopaedic trauma, vascular and medical oncology units without breaks in the skin (Waterlow score ≥ 15) **Exclusion criteria**: not described **Sex (M:F)**: overall 66:104; 33:57 in Softfoam mattress; 33:47 in Standard 130 mm NHS foam mattress **Age (years)**: overall mean 76 (range 35 to 99); mean 76 (SD 10.53) in Softfoam mattress; 74 (9.96) in Standard 130 mm NHS foam mattress **Baseline skin status**: mean Waterlow 18.03 (SD 3.23) in Softfoam mattress; 16.01 (2.58) in Standard 130 mm NHS foam mattress **Group difference**: no difference **Total number of participants**: n = 170 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Softform mattress • **Description of interventions**: Softform mattress ... supplied by Medical Support Systems Ltd (Cardiff) (Gray 1994); " A high specification foam mattress ... " from Invacare website (https://www.invacare.co.uk/invacare-softform-premier-maxiglide-mattress-ma-83sfpremgen) • **NPIAP S3I classification:** non-powered, reactive foam surface; high-specification foam • **Co-interventions**: not described • **Number of participants randomised**: n = 90 • **Number of participants analysed**: not given Standard 130 mm foam mattress • **Description of interventions**: standard 130 mm foam mattresses ... supplied by Recticel Ltd. (Midlands) • **NPIAP S3I classification:** non-powered, reactive foam surface • **Co-interventions**: not described • **Number of participants randomised**: n = 80 • **Number of participants analysed**: not given
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not described • **Reporting**: partially reported

- **Measurement method (e.g. scale, self-reporting)**: not described
- **Definition (including ulcer stage)**: not described
- **Dropouts**: not described
- **Notes (e.g. other results reported)**: percentage of participants developing new ulcers 7.1% (n = 6) in Softform; 34.2% in standard, Chi^2 $P < 0.001$

Time to pressure ulcer incidence

- **Reporting:** not reported

Support-surface-associated patient comfort

- **Outcome type**: categorical
- **Time points**: not described
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: assessed using a standardised question and a visual rating scale, administered: 'Which phrase best describes the mattress you have occupied during your stay in hospital?' (very uncomfortable, uncomfortable, adequate, comfortable, very comfortable, no response obtained)
- **Definition**: not described
- **Dropouts**: no missing
- **Notes**: very uncomfortable 0/ uncomfortable 0/ adequate 6/ comfortable 62/ very comfortable 11/ no response 11 of 90 in Softform; 0/2/44/26/0/8 of 80 in standard. comfortable or very comfortable 81.1% in Softform, 32.5% in standard

All reported adverse events using allocated support surfaces

- **Reporting:** not reported

Health-related quality of life (HRQOL)

- **Reporting:** not reported

Cost-effectiveness

- **Reporting:** not reported

Outcomes that are not considered in this review but reported in trials:

- No

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Allocation of mattresses was by patient randomisation on admission ... randomly allocated to one of the two types of mattress using unmarked envelopes" Comment: unclear if a proper randomisation method was applied.
Allocation concealment (selection bias)	Unclear risk	Quote: "randomly allocated to one of the two types of mattress using unmarked envelopes" Comment: unclear if allocation was appropriately concealed.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Comment: no information provided.

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: pressure ulcer outcome*** Comment: no information provided. ***Outcome group: comfort outcome*** Comment: high risk of bias because it is unlikely that patients who self-reported their comfort responses are blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Quote: "A number of patients were excluded from the study because the Waterlow score awarded by the ward staff differed greatly from that of the researcher" Comment: unclear risk of bias because the number of exclusions is unclear and unclear if this exclusion was post-randomisation.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Gray 2000

Study characteristics	
Methods	**Study objective**: to evaluate the ability of 2 pressure-reducing mattresses to prevent pressure sores in a population who were deemed to be at high risk of sore development. **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 10 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: acute care settings of a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: patients admitted to a district general hospital (either emergency or planned admission) for bed-rest or surgery, with intact skin, no other skin abnormalities, no terminal illness, weight < 160 kg **Exclusion criteria**: not given **Sex (M:F)**: 30:20 in Transfoamwave; 31:19 in Transfoam **Age (years)**: mean 69 (SD 4.5) in Transfoamwave; 61 (4.1) in Transfoam **Baseline skin status**: mean Waterlow 13 (SD 2.5) in Transfoamwave; Waterlow 14 (3.6) in Transfoam; no existing ulcers **Group difference**: no difference **Total number of participants**: n = 100 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Transfoam • **Description of interventions**: constructed using foams of varying densities, with uncut surfaces (Gray 2000); "in the viscoelastic foam mattress there is a base layer of robust polyurethane ... " from Beldon 2002. • **NPIAP S3I classification:** non-powered, reactive foam surface;

	high-specification foam • **Co-interventions**: not described • **Number of participants randomised**: n = 50 • **Number of participants analysed**: n = 50 Transfoamwave • **Description of interventions**: constructed using foams of varying densities, with uncut surfaces • **NPIAP S3I classification:** non-powered, reactive foam surface; high-specification foam • **Co-interventions**: not described • **Number of participants randomised**: n = 50 • **Number of participants analysed**: n = 50
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 10 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: graded using the Torrance scale • **Definition (including ulcer stage)**: pressure ulcer incidence of any stages • **Dropouts**: not reported • **Notes (e.g. other results reported)**: 1 participant with Grade 2 in Transfoamwave; 1 with Grade 4 in Transfoam. Additionally, 1 participant in each group having non-blanching erythema *Time to pressure ulcer incidence* • **Reporting:** not reported *Support-surface-associated patient comfort* • **Outcome type**: categorical • **Time points**: not described • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: comfort ratings, on a 5 point scale from ‘very uncomfortable’ to ‘very comfortable' • **Definition**: not reported • **Dropouts**: 2 of 50 in Transfoam and 3 of 50 in Transfoamwave missed • **Notes**: very uncomfortable 0/ uncomfortable 0/ adequate 3/ comfortable 26/ very comfortable 18 of 47 in Transfoamwave; 0/1/2/34/11 of 48 in Transfoam *All reported adverse events using allocated support surfaces* • **Reporting:** not reported *Health-related quality of life (HRQOL)* • **Reporting:** not reported *Cost-effectiveness* • **Reporting:** not reported

Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Individuals who met the entry criteria were randomised to a control or trial mattress using an opaque envelope" Comment: unclear if a proper randomisation method was applied.
Allocation concealment (selection bias)	Unclear risk	Quote: "Individuals who met the entry criteria were randomised to a control or trial mattress using an opaque envelope" Comment: unclear if allocation was concealed.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: pressure ulcer outcome*** Quote: "Tissue damage was assessed by staff who were unaware which mattress the subject was using" Comment: low risk of bias because blinded outcome assessors were used for the comparison of 2 foam mattresses. This blinding is feasible. ***Outcome group: comfort outcome*** Comment: high risk of bias because it is unlikely that it was possible to blind patient self-reported outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	***Outcome group: pressure ulcer outcome*** Comment: unclear risk of bias because the number of individuals with data observed was not specified. ***Outcome group: comfort outcome*** Comment: low risk of bias because in total 5 of 100 missed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Gunningberg 2000

Study characteristics	
Methods	**Study objective**: to investigate if viscoelastic foam mattresses are more effective than standard hospital mattresses in reducing the incidence of pressure ulcers in patients with hip fractures. **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: post-operative 14 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: March and December 1999 **Setting**: accidents and emergency (A&E) department and the orthopaedic wards of a university hospital

Participants	**Baseline characteristics** **Inclusion criteria**: patients aged over 65 years with a suspected hip fracture **Exclusion criteria**: died, did not have a skin assessment documented on arrival, admitted with pressure ulcers **Sex (M:F)**: 10:38 in viscoelastic foam mattress; 10:43 in standard hospital mattress **Age (years)**: mean 84 (range 66 to 102) in viscoelastic foam mattress; 85 (67 to 96) in standard hospital mattress **Baseline skin status**: mean Modified Norton score (at risk = a total score of ≤ 21): 18.6 (range 10 to 25) in viscoelastic foam mattress; 18.8 (11 to 24) in standard hospital mattress; excluding those with pressure ulcers **Group difference**: no difference **Total number of participants**: 101 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Viscoelastic foam mattress • **Description of interventions**: placed on a 10-centimetre thick viscoelastic foam mattress (7 cm viscoelastic foam plus 3 cm 35 kg/m^3 foam: Tempur-Pedic, Fagerdala, Sweden) immediately on arrival in A&E. A 7 cm viscoelastic foam overlay was placed on the standard mattresses used in the wards. • **NPIAP S3I classification:** non-powered, reactive foam surface; high-specification foam (viscoelastic foam plus density of 35 kg/m^3) • **Co-interventions**: not described • **Number of participants randomised**: n = 48 • **Number of participants analysed**: n = 48 Standard hospital mattress • **Description of interventions**: placed on the routine standard trolley (5 cm mattress) and then on the standard hospital mattress (10 cm foam 50 kg/m^3: Prodenso, Ranson AB, Sweden) when transferred to the ward • **NPIAP S3I classification**: standard hospital surface • **Co-interventions**: not described • **Number of participants randomised**: n = 53 • **Number of participants analysed**: n = 53
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 2 weeks • **Reporting:** fully reported • **Measurement method (e.g. scale, self-reporting)**: ward nurses rated and expert nurses confirmed • **Definition (including ulcer stage)**: presence or absence of a pressure ulcer (including grade I ulcers) graded by NPUAP system • **Dropouts**: no dropouts • **Notes (e.g. other results reported)**: 12 of 48 in viscoelastic foam mattress (8 Grade I; 4 Grade II; 0 Grade III, 0 Grade IV); 17 of 53 in standard hospital mattress (9 Grade I; 7 Grade II; 0 Grade III; 1 Grade IV)

	Time to pressure ulcer incidence • **Reporting:** not reported *Support-surface-associated patient comfort* • **Outcome type**: continuous • **Time points**: 2 weeks • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: self-rated using a standardised question: 'How did you experience the comfort of the hospital mattress?' and 'very good' = 5, 'good' = 4, 'adequate' = 3, 'bad' = 2 and 'very bad' = 1 • **Definition**: patients' perceptions of mattress comfort • **Dropouts**: 27 dropouts in viscoelastic foam mattress; 33 in standard hospital mattress • **Notes**: mean rating of comfort: 4.2 in viscoelastic foam mattress; 4.0 in standard hospital mattress; 38 of 41 reported good or very good comfort in both groups *All reported adverse events using allocated support surfaces* • **Reporting:** not reported *Health-related quality of life (HRQOL)* • **Reporting:** not reported *Cost-effectiveness* • **Reporting:** not reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "On arrival in A&E patients with a suspected hip fracture were randomised to an experimental or a control group with concealed allocation" Comment: the method of randomisation was not reported.
Allocation concealment (selection bias)	Unclear risk	Quote: "On arrival in A&E patients with a suspected hip fracture were randomised to an experimental or a control group with concealed allocation" Comment: the method of concealing allocation was not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: primary outcome*** Quote: "The pressure ulcer nurse on the ward usually performed the assessments on the fourth postoperative day and at discharge. The pressure ulcers were photographed ... The ulcers in these photos were graded by an expert nurse ... who was blinded to treatment, and compared with the classifications performed by the nurses in A&E and on the wards ... an excellent agreement" Comment: low risk of bias because the expert nurse who was blinded to treatment had assessments consistent with the ward nurses, meaning ward nurses' outcome assessment was unlikely to be influenced by treatment.

		Outcome group: comfort outcome Comment: high risk of bias because it is impossible to blind patients to self-reported outcome measure.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: primary outcome*** Comment: no missing data. ***Outcome group: comfort outcome*** Quote: "Forty-one patients (21 in the experimental and 20 in the control group) with a mean age of 84 years (SD: 7.6, 67–102) answered this question" Comment: high risk of bias because 27 of 48 in viscoelastic foam group and 33 of 53 in standard hospital mattress group missed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Hofman 1994

Study characteristics	
Methods	**Study objective**: to determine the effectiveness in pressure-sore prevention of the DeCube mattress versus standard mattress in patients with a femoral-neck fracture and a concomitant high risk for the development of pressure sores. **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 1 and 2 weeks **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: hospital
Participants	**Baseline characteristics** **Inclusion criteria**: all patients admitted to hospital with a femoral-neck fracture and with a pressure-sore risk score of 8 points or more **Exclusion criteria**: patients with pressure sores of grade 2 or more on admittance **Sex (M:F)**: 5:16 in DeCube mattress; 1:22 in standard mattress **Age (years)**: mean 85.0 (SD 8.1) in DeCube mattress; 83.9 (6.9) in standard mattress **Baseline skin status**: mean score 10 (SD 1.6) in DeCube mattress; 10.4 (1.4) in standard mattress. All at high risk (according to a scale in the 1985 Dutch consensus meeting, score ≥ 10) **Group difference**: no difference **Total number of participants**: 46 individuals randomised (2 incorrectly randomised); 42 analysed at 1 week; 36 analysed at 2 weeks **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Comfortex DeCube mattress • **Description of interventions**: Comfortex DeCube mattress (Comfortex, Winona, USA) but no further description. "an orthopaedic technician developed a mattress with a foam core and multiple small cubes that could be removed beneath bony prominences for pressure relief, similar to the

	DeCube Comfortex mattress" (Hofman 1994); "Highly resilient layer of cushioning materials spans over surface and conforms to the body" from product description in Direct Supply (https://store.directsupply.com/Product/decube-foam-mattress-2519567). • **NPIAP S3I classification:** non-powered, reactive foam surface; high-specification (high resilience) foam • **Co-interventions**: standard protocol • **Number of participants randomised**: n = 23 (2 incorrectly randomised) • **Number of participants analysed**: n = 20 at 1 week; 17 at 2 weeks Standard hospital mattress • **Description of interventions**: standard Vredestein polypropylene SG 40 hospital mattress (Vredestein, Netherlands) • **NPIAP S3I classification**: standard hospital surface • **Co-interventions**: standard protocol • **Number of participants randomised**: n = 23 • **Number of participants analysed**: n = 22 at 1 week; 19 at 2 weeks
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 1 week; 2 weeks • **Reporting:** fully reported • **Measurement method (e.g. scale, self-reporting)**: graded using 0 = normal skin; 1 = persistent erythema of the skin; 2 = blister formation; 3 = superficial (sub)cutaneous necrosis; and 4 = deep subcutaneous necrosis • **Definition (including ulcer stage)**: number of patients with maximum pressure-sore gradings on any location and defined grade 2 or more as clinically relevant pressure sores • **Dropouts**: 3 of 23 in DeCube and 1 of 23 in standard mattress at 1 week; 6 of 23 in DeCube and 4 of 23 in standard at 2 weeks • **Notes (e.g. other results reported)**: 1 week data: 5 of 20 in DeCube (3 grade 2, 1 grade 3, and 1 grade 4) and 14 of 22 in standard (4 grade 2 and 10 grade 3); 2-week data: 4 of 17 in DeCube (1 grade 2 and 3 grade 3) and 13 of 19 in standard (5 grade 2, 5 grade 3 and 3 grade 4) *Time to pressure ulcer incidence* • **Reporting:** not reported *Support-surface-associated patient comfort* • **Reporting:** not reported *All reported adverse events using allocated support surfaces* • **Reporting:** not reported *Health-related quality of life (HRQOL)* • **Reporting:** not reported *Cost-effectiveness* • **Reporting:** not reported **Outcomes that are not considered in this review but reported in trials**: • Pressure ulcer incidence by sacrum, trochanters, shoulders, left hip fracture and right hip fracture (reported by authors but not extracted)

Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Each group of 6 consecutively admitted patients was randomly divided into 3 patients nursed preoperatively and postoperatively on the standard Vredestein polyproleen [polypropylene] SG 40 hospital mattress (Vredestein, Netherlands) and 3 nursed on the Comfortex DeCube" Comment: the method of randomisation was not described.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "The study was not blinded with respect to observer or nurse" Comment: high risk of bias because clearly blinding was not implemented.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "The study was not blinded with respect to observer or nurse" Comment: high risk of bias because clearly blinding was not implemented.
Incomplete outcome data (attrition bias) All outcomes	High risk	***Outcome group: primary outcomes*** Comment: high risk of bias because 10 of 46 individuals missed at 2 weeks.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Unclear risk	Comment: the study appears to have been stopped early. It is not clear whether this interim analysis was pre-planned in advance of data collection - the sample size calculation doesn't seem to take this into account.

Hoshowsky 1994

Study characteristics	
Methods	**Study objective**: to examine the effects of 2 operating room (OR) table mattresses and 1 mattress overlay on intraoperative pressure sore formation **Study design**: randomised controlled trial **Study grouping**: parallel group (split body design) **Duration of follow-up**: not given **Number of arms**: 4 different treatment protocols (made up from 3 types of mattresses) tested in 6 different pairings **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: university teaching hospital
Participants	**Baseline characteristics** **Inclusion criteria**: patients in the study were placed in the supine or prone positions while undergoing surgery, older than 12 years of age, and possession of symmetrical lower limbs **Exclusion criteria**: not given

	Sex (M:F): overall 184:321 (across all 6 comparisons) **Age (years)**: overall mean 47 years (SD 17.1) and range 13 to 86 (across all 6 comparisons) **Baseline skin status**: not given **Group difference**: no difference within each comparison (due to within-person comparison made) **Total number of participants**: standard foam mattress (SFM) vs. foam and gel mattress (FGM): n = 91; VEO-Action above SFM vs. FGM n = 92; SFM versus VEO above FGM n = 62; VEO above SFM versus VEO above FGM n = 113; SFM versus VEO above SFM n = 73; and FGM versus VEO above FGM n = 74 (overall 505 across 6 comparisons) **Unit of analysis**: treatment sessions of individuals **Unit of randomisation (per patient)**: treatment sessions of individuals
Interventions	**Intervention characteristics** Standard foam mattress • **Description of interventions**: a standard vinyl covered 2-inch thick foam OR table mattress (SFM) • **NPIAP S3I classification:** non-powered, reactive foam surface • **Co-interventions**: not described • **Number of participants randomised**: this intervention was involved in 3 comparisons and each had a different numbers of participants (see above) • **Number of participants analysed**: not given Foam and gel mattress (FGM) • **Description of interventions**: a nylon fabric covered 2-inch thick foam and gel OR table mattress (FGM - Akros®, American Sterilizer Co.) • **NPIAP S3I classification:** non-powered, reactive foam plus gel surface • **Co-interventions**: not described • **Number of participants randomised**: this intervention was involved in 3 comparisons and each had a different numbers of participants (see above) • **Number of participants analysed**: not given VEO-Action® • **Description of interventions**: a viscoelastic dry polymer mattress overlay (VEO-Action® , Action Products Inc.) • **NPIAP S3I classification:** non-powered, reactive gel surface • **Co-interventions**: not described • **Number of participants randomised**: this intervention was involved in 5 comparisons and each had a different numbers of participants (see above) • **Number of participants analysed**: not given
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: not given • **Time points**: not given • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: all skin changes noted; blanchable hyperaemic areas classified as skin changes and non-blanchable hyperaemic areas classified as Stage I pressure sores, in accordance with the NPIAP staging system • **Definition (including ulcer stage)**: not specified with details; skin change

	and ulcer incidence • **Dropouts**: not described • **Notes (e.g. other results reported)**: none of the 505 patients developed pressure sores of severity Stages II through IV; Stage I pressure sores in 85 patients (16.8%); skin changes that did not reach Stage I in 290 patients (57.4%). Odds of developing pressure ulcer with viscoelastic overlay (versus standard hospital mattress) 0.40 (95% CI 0.21 to 0.77); however, the related logistic regression as described does not appear to take into account the multiple measures per person. *Time to pressure ulcer incidence* • **Not reported** *Support-surface-associated patient comfort* • **Not reported** *All reported adverse events using allocated support surfaces* • **Not reported** *Health-related quality of life (HRQOL)* • **Not reported** *Cost-effectiveness* • **Not reported**
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: unclear risk of bias because each patient served as their own control but within the patient, the allocation of interventions was unspecified.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Outcome group: ulcer incidence. Quote: "Use of the overlay in this manner prevented the investigators from being blinded at the time of postoperative assessment whenever the overlay was used." Comment: high risk of bias because non-blinding is clearly stated.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome group: ulcer incidence. Quote: "Use of the overlay in this manner prevented the investigators from being blinded at the time of postoperative assessment whenever the overlay was used." Comment: high risk of bias because non-blinding is clearly stated.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: no information provided.
Selective reporting (reporting bias)	Unclear risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes. No data are reported on the number or rate of pressure ulcers by group and this would be expected. Only statistically significant odds were reported.

Other bias	High risk	Comment: the study appears to consider parts of a person's body as unit of analysis. However, the logistic regression as described does not appear to take into account the multiple measures per person.

Kemp 1993

Study characteristics	
Methods	**Study objective**: to compare the effectiveness of 2 types of overlays intended to prevent pressure ulcers: a convoluted foam mattress overlay and a solid foam mattress overlay **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 1 month **Number of arms**: 2 **Single centre or multi-sites**: multi-sites **Study start date and end date**: March 1989 and November 1989 **Setting**: a tertiary-care medical centre (acute setting) and a long-term care facility
Participants	**Baseline characteristics** **Inclusion criteria**: patients without pressure ulcers who are at least 65 years old and had a Braden score of 16 or less (at risk) **Exclusion criteria**: not described **Sex (M:F)**: 26:58 overall; 14:31 in convoluted foam; 12:27 in solid foam **Age (years)**: overall mean 81 (SD 8); 79.31 (7.54) in convoluted foam and 82.64 (8.60) in solid foam **Baseline skin status**: mean Braden score 14.00 (SD 1.73) in convoluted foam; 13.85 (1.71) in solid foam **Group difference**: no difference **Total number of participants**: 84 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals

Interventions	**Intervention characteristics** Convoluted foam mattress overlay • **Description of interventions**: either a 3-inch overlay with a density of 1.42 lb per cubic foot or a 4-inch overlay (density unknown) • **NPIAP S3I classification:** non-powered, reactive foam surface; foam with a density of 22.7 kg/m^3 • **Co-interventions**: not described • **Number of participants randomised**: n = 45 • **Number of participants analysed**: n = 45 Solid foam mattress overlay • **Description of interventions**: a 4-inch solid, sculptured overlay with a density of 1.33 lb per cubic foot • **NPIAP S3I classification**: non-powered reactive foam surface; foam with a density of 21.3 kg/m^3 • **Co-interventions**: not described • **Number of participants randomised**: n = 39 • **Number of participants analysed**: n = 39
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 1 month • **Reporting:** fully reported • **Measurement method (e.g. scale, self-reporting)**: assessed by research nurses using NPIAP 1989 system • **Definition (including ulcer stage)**: no. of patients with pressure ulcers of any grade • **Dropouts**: no missing data • **Notes (e.g. other results reported)**: 21 of 45 in convoluted foam; 12 of 39 in solid foam. All grade 1 and 2 ulcers; no grade 3 or grade 4 ulcers *Time to pressure ulcer incidence* • **Reporting**: partially reported • **Notes (e.g. other results reported)**: hazard ratio for convoluted foam vs solid foam of exp(0.906) = 2.47 and P = 0.018 in a Cox regression model adjusted for mobility score (solid foam as reference); 'The positive coefficient (0.906) for overlay type indicated that the risk of developing a pressure ulcer was greater for patients nursed on convoluted foam than for patients nursed on solid foam when the averaged mobility score was also taken into account'; estimated HR 2.47 (95% CI 1.25 to 4.90) (or lnHR 0.906, se 0.35). Note that the averaged mobility scores were adjusted for by the study authors rather than scores at baseline. *Support-surface-associated patient comfort* • **Reporting:** not reported *All reported adverse events using allocated support surfaces* • **Reporting:** not reported *Health-related quality of life (HRQOL)* • **Reporting:** not reported *Cost-effectiveness*

	• **Reporting:** not reported
Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "At each clinical site, a random number table was used to assign study patients to ..." Comment: low risk of bias because of the use of a random number table.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "The research nurses recorded their skin assessments on a form developed for this study" Comment: unclear risk of bias because no information on blinding provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no missing data.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Laurent 1998

Study characteristics	
Methods	**Study objective**: to assess the effectiveness of 3 prevention strategies and compare them to the standard mattress **Study design**: randomised controlled trial **Study grouping**: factorial design **Duration of follow-up**: mean length of stay 15.04 (SD 7.10) **Number of arms**: 4 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: hospital
Participants	**Baseline characteristics** **Inclusion criteria**: adults over 15 years of age, admitted for major cardiovascular surgery, hospital stay likely to be at least 5 days, with a period in the intensive care unit (ICU) **Exclusion criteria**: not reported **Sex (M:F)**: 214:98 across 4 groups **Age (years)**: mean 64.0 (SD 11.88) across 4 groups

	Baseline skin status: not described **Group difference**: no difference **Total number of participants**: n = 312 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Standard group • **Description of interventions**: standard mattress in ICU; standard mattress postoperatively • **NPIAP S3I classification**: standard hospital surface (ICU); standard hospital surface (postoperation) • **Co-interventions**: not described • **Number of participants randomised**: n = 80 • **Number of participants analysed**: n = 80 Alternating mattress in ICU • **Description of interventions**: Nimbus (AP) in ICU; standard mattress postoperatively • **NPIAP S3I classification:** powered, alternating pressure (active) air surface (ICU); standard hospital surface (postoperation) • **Co-interventions**: not described • **Number of participants randomised**: n = 80 • **Number of participants analysed**: n = 80 Constant low-pressure mattress in postoperative hospitalisation • **Description of interventions**: standard mattress in ICU; Tempur (CLP) postoperatively (Laurent 1998). Additional source of information: "a visco-elastic polyethylene urethane foam mattress (Tempur®, Tempur-World Inc., USA)" (Vanderwee 2005). • **NPIAP S3I classification**: standard hospital surface (ICU); non-powered reactive foam surface; high specification viscoelastic foam (postoperation) • **Co-interventions**: not described • **Number of participants randomised**: n = 75 • **Number of participants analysed**: n = 75 Both mattresses • **Description of interventions**: Nimbus in ICU and Tempur (CLP) postoperatively • **NPIAP S3I classification:** powered, alternating pressure (active) air surface (ICU); non-powered reactive foam surface; high specification viscoelastic foam (postoperation) • **Co-interventions**: not described • **Number of participants randomised**: n = 77 • **Number of participants analysed**: n = 77
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not described • **Reporting**: partially reported

	• **Measurement method (e.g. scale, self-reporting)**: assessed by specially trained nurses and classified as stage 0 (normal skin), stage 1 (non-blanchable erythema), and stage 2 (partial or full thickness skin loss) • **Definition (including ulcer stage)**: cumulative incidence of pressure sores of stage 2 (the lower the rate, the better the mattress effectiveness) • **Dropouts**: not described • **Notes (e.g. other results reported)**: 45 of 312 (14.4%) having pressure sores; 14 of 80 in standard; 10 of 80 in alternating mattress in ICU; 11 of 75 in constant low pressure mattress; 10 of 77 in both mattresses *Time to pressure ulcer incidence* • **Reporting:** not reported *Support-surface-associated patient comfort* • **Reporting:** not reported *All reported adverse events using allocated support surfaces* • **Reporting:** not reported *Health-related quality of life (HRQOL)* • **Reporting:** not reported *Cost-effectiveness* • **Reporting**: not reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomised by blocks" Comment: unclear risk of bias because the randomisation method was not stated.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "Given the kind of material tested, blinding was not possible" Comment: high risk of bias as the above statement suggests.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "Given the kind of material tested, blinding was not possible" Comment: high risk of bias as the above statement suggests.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: primary outcome*** Comment: no attrition identified.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	High risk	Comment: the study appears not to consider the interaction between the effects of the different interventions that results from the factorial design used.

Nixon 2019

Study characteristics	
Methods	**Study objective**: to compare clinical and cost-effectiveness of 2 mattress types: alternating pressure mattresses (APMs) or high specification foam (HSF) **Study design:** randomised controlled trial (double triangular group sequential design) **Study grouping**: parallel group **Duration of follow-up**: maximum treatment phase of 60 days; 30 days post-treatment **Number of arms:** two **Single centre or multi-sites:** multi-sites **Study start date and end date**: August 2013 to November 2016 **Setting**: 42 UK secondary/community inpatient facilities
Participants	**Baseline characteristics** **Inclusion criteria**: inpatient with evidence of acute illness; ≥ 18 years; expected stay ≥ 5 days; expected to comply with follow-up; on electric profiling bed-frame; high pressure ulcer risk due to at least 1 of following: Braden activity score 1/2 and mobility score 1/2; category 1 ulcers; localised skin pain on a healthy/altered /category 1 pressure area **Exclusion criteria**: had previously participated; current/previous ulcer category ≥ 3; planned intensive care unit (ICU) admission; unable to receive intervention; out of mattress weight limits (< 45 kg or > 180 kg); ethically inappropriate (e.g. thought to be in the last few days of their life). **Sex (M:F)**: 907:1119 overall; 462:553 in APM; 445:566 in HSF **Age (years)**: median 81 (range 21 to 105) overall; mean 77.8 (SD 13.42) in APM; 78.2 (12.87) in HSF **Baseline skin status**: overall 78 with a Braden score > 18 (not at risk) in APM and 69 in HSF; 937 with a score ≤ 18 (at risk) in APM; 942 in HSF. At risk and allowed to have category 1 ulcers. **Group difference**: no difference **Total number of participants:** n = 2029 **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Alternating pressure air mattress (APM) • **Description of interventions**: fully automatic; some may have dual therapy; for example, the mattress comprises a combination of alternating pressure or low-air-loss. The trial will include only those participants nursed on the alternating pressure mode of action, with a 7.5 to 30 minute cycle time. • **NPIAP S3I classification:** powered, alternating pressure (active) air surface • **Co-interventions**: not reported • **Number of participants randomised**: n = 1017 • **Number of participants analysed**: n = 1016 High-specification foam mattress (HSF) • **Description of interventions**: be a high-density foam, viscoelastic (memory) foam or a combination of both, and can be castellated (for ventilation and profiling). Have a cover with the following characteristics: removable, minimum two-way stretch, vapour permeable and covered zips as defined in BS 3379.36. Be a replacement mattresses with a minimum depth of 150–200 mm

	• **NPIAP S3I classification**: non-powered, reactive foam surface • **Co-interventions**: not reported • **Number of participants randomised**: n = 1013 • **Number of participants analysed**: n = 1013
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 90 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: classified using the 2009 NPIAP/EPUAP system • **Definition (including ulcer stage)**: incidence of pressure ulcer (PU) category ≥ 2 from randomisation to 30 days from the end of the treatment phase (maximum of 90 days) • **Dropouts**: intention-to-treat (ITT) analysis but 1 participant excluded from alternating pressure mattress due to the person's previous inclusion/randomisation • **Notes (e.g. other results reported)**: ***primary time point (90 days)*** : 70 of 1016 (6.9%) in alternating pressure air mattress; 90 of 1013 (8.9%) in high-specification foam mattress. ***Data from randomisation to end of treatment (60 days)*** : 53 of 1016 (5.2) in alternating pressure air mattress; 79 of 1013 (7.8%) in high-specification foam mattress. ***Seconday endpoint (incidence of a new PU category ≥ 1 by 90 days)*** : 160 of 1016 in alternating pressure air mattress; 190 of 1013 in high-specification foam mattress. ***Seconday endpoint (incidence of a new PU category ≥ 3 by 90 days)*** : 14 of 1016 vs 18 of 1013 *Time to pressure ulcer incidence* • **Outcome type**: time-to-event • **Time points**: maximum 90 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: classified using the 2009 NPIAP/EPUAP system • **Definition (including ulcer stage)**: time to developing a new PU category ≥ 2 from randomisation to 30 days from the end of the treatment phase (maximum of 90 days) • **Dropouts**: ITT analysis but 1 participant excluded from alternating pressure mattress due to the person's previous inclusion/randomisation. • **Notes (e.g. other results reported)**: ***primary time point (90 days):*** median time to first new ulcer 18 days (range 2 to 86) in alternating pressure air mattress; 12 (2 to 94) in high-specification foam mattress; adjusted analysis Fine and Gray model HR 0.76 (95% CI 0.56 to 1.04, exact P = 0.0890). ***Data within 60 days*** : Fine and Gray model HR 0.66 (95% CI 0.46 to 0.93; exact P = 0.0176). Seconday endpoint (incidence of a new PU category ≥ 1 by 90 days): Fine and Gray model HR 0.83 (95% CI 0.67 to 1.02; exact P 0.0733). ***Seconday endpoint (incidence of a new PU category ≥ 3 by 90 days)*** : HR 0.81 (95% CI 0.40 to 1.62); exact P 0.5530. Univariate survival analysis curves presented in Fig 2. *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events* • **Outcome type**: binary

- **Time points**: 90 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**:
- **Definition (including ulcer stage)**:
- **Dropouts**: ITT analysis but 1 participant excluded from alternating pressure mattress due to the person's previous inclusion/randomisation
- **Notes (e.g. other results reported)**: no safety concerns indicated for either mattress. No related and unexpected serious adverse events in either group. Expected adverse events/serious adverse events: 163 of 1017 in APM and 167 of 1013 in HSFM. The proportion of deaths (APM 82/1017, 8.1% vs. HSFM 84/1013, 8.3%), re-admission rates (APM 82/1017, 8.1% vs. HSFM 62/1013, 6.1%) and fall rates (APM 152/1017, 14.9% vs. HSFM 159/1013, 15.7%) similar between arms

Health-related quality of life (HRQOL)

- **Outcome type**: binary
- **Time points**: 90 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: HRQOL assessed using the EQ-5D-5L and quality-adjusted life-years (QALY) calculated based on EQ-5D-5L using an equation QALY = {[(EQ5DBaseline + EQ5Dweek1) × t]/ 2 + [(EQ5Dweek1 + EQ5Dweek3) × t]/ 2 + [(EQ5Dweek3 + EQ5DEndpoint) × t)]/2}. Sensitivity analysis performed with HRQOL measure of PU-QoL-UI. The utility values of the EQ-5D-5L and PU-QoL-UI have a scale of negative 1 to 1, with 1 representing perfect health, 0 representing death, and − 1 representing worse than death.
- **Definition (including ulcer stage)**: mean estimated QALYs
- **Dropouts**: 267 participants (APM arm, n = 118; HSFM arm, n = 149) completed the EQ-5D-5L at all 4 time points, and 233 had completed the PU-QoL-UI at all 4 time points (APM arm, n = 107; HSFM arm, n = 126)
- **Notes (e.g. other results reported)**: ***90-day EQ-5D-5L*** : mean 0.52 (SD 0.21) in APM, 0.52 (0.22) in HSF; P = 0.49. Mean QALYs higher in alternating pressure air mattress 0.128 (95% 0.126 to 0.130) than high-specification foam mattress 0.127 (0.124 to 0.129); P = 0.47. ***90-day PU-QoL-UI*** : mean 0.69 (SD 0.13) in APM, 0.69 (0.13) in HSF; P = 0.28

Cost-effectiveness

- **Outcome type**: binary
- **Time points**: 90 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: an ITT analysis used quality-adjusted life-years (QALYs) as the main outcome and adopted the perspective of the UK National Health Service (NHS) and Personal Social Services (PSS). The NICE £20,000 per QALY gained threshold was used to determine cost-effectiveness. Utility values were derived from the EQ-5D-5L, and costs were estimated using the UK tariff. Costs and outcomes were adjusted for baseline imbalances. Sampling uncertainty was determined via a probabilistic sensitivity analysis (PSA) using a non-parametric bootstrap.
- **Definition (including ulcer stage)**: the incremental cost per QALY gained; within-trial analyses using QALYs derived from the EQ-5D-5L
- **Dropouts**: ITT analysis
- **Notes (e.g. other results reported)**: adjusted for baseline costs and QALYs, deterministic analysis suggests the mean total costs of APM and HSFM are GBP 4,533 and GBP 4,646, respectively, with mean QALYs of 0.128 and

	0.127, respectively. Incremental cost-effectiveness ratio (ICER) = GBP –136,171; net-monetary benefit (NMB) = GBP –2077; probabilistic analysis shows mean total costs of APM and HSFM are GBP 4,533 and GBP 4,646, respectively, and mean QALYs are 0.128 and 0.127, respectively. ICER = –101,699 and NMB = –2114. Estimates indicate that APM has a 99% probability of being cost-effective at a threshold of GBP 20,000 (APMs dominate HSFM, as APM has lower costs and higher QALY values). Lifetime decision-analytic model developed for lifetime cost-effectiveness analysis but data not extracted for this review. Finding is: APM to be cost-effective over both the short and the long term. **Outcomes that are not considered in this review but reported in trials**: • Time to healing of all pre-existing category 2 ulcers • Mattress compliance
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Participants were randomised centrally (24 h automated telephone system, ensuring allocation concealment) on a 1:1 basis using minimisation (with random element) and minimisation factors: centre, PU status, type of facility, and type of consent" Comment: low risk of bias because of the use of a proper randomisation method.
Allocation concealment (selection bias)	Low risk	Quote: "Participants were randomised centrally (24 h automated telephone system, ensuring allocation concealment) on a 1:1 basis using minimisation (with random element) and minimisation factors: centre, PU status, type of facility, and type of consent" Comment: low risk of bias because allocation is properly concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Blinding of the research and clinical staff or patients was not possible due to the appearance of the mattresses" Comment: high risk of bias because non-blinding is clearly stated.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Assessment of risk of bias of the primary endpoint was done with central blind review of photographs and a 10% sample of patients who had skin assessments by a practitioner blinded to previous assessments was performed" Comment: low risk of bias because attempts were made to mask outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "All participants recruited were included using Intention-To-Treat (ITT) and analysed by randomised allocation" Comment: low risk of bias because ITT analysis was performed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is available and it is clear that the published reports include all outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Ozyurek 2015

Study characteristics	
Methods	**Study objective**: to compare whether differences exist between 2 viscoelastic foam support surfaces in the development of new pressure ulcers

	Study design: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: not specified; length of stay 17.36 days (SD 17.9) **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: October 2008 and January 2010 **Setting**: medical and surgical intensive care units of a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: patients older than 18 years whose expected length of stay was at least 7 days **Exclusion criteria**: those with a pressure ulcer (PU) of stage 1 or worse on admission or weighed more than 140 kg or less than 45 kg (as per mattress recommendations); those with Braden score higher than 18 (no risk) **Sex (M:F)**: 26:27 in foam 1; 29:23 in foam 2 **Age (years)**: 64.99 (15.10) across groups; mean 64.77 (SD 15.09) in foam 1; 65.21 (15.26) in foam 2 **Baseline skin status**: mean Braden score 14.11 (SD 3.35) in foam 1; 13.06 (2.79) in foam 2 **Group difference**: no difference **Total number of participants**: 357 randomised; 105 analysed **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Viscoelastic foam 1 • **Description of interventions**: viscoelastic polyurethane foam 1, composed of 2 layers, a 7 cm support surface with 8 cm of high-flexibility foam • **NPIAP S3I classification**: non-powered, reactive foam surface; multi-layered, viscoelastic polyurethane, high-flexibility foam • **Co-interventions**: repositioning, nutrition support • **Number of participants randomised**: n = 178 • **Number of participants analysed**: n = 53 Viscoelastic foam 2 • **Description of interventions**: a breathable, open-cell type of viscoelastic foam, was composed of 3 layers, the top active viscoelastic layer, lower support layer, and side safety barrier • **NPIAP S3I classification**: non-powered, reactive foam surface; multi-layered, viscoelastic foam • **Co-interventions**: repositioning, nutrition support • **Number of participants randomised**: n = 179 • **Number of participants analysed**: n = 52
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: mean length of stay 17 days • **Reporting:** fully reported • **Measurement method (e.g. scale, self-reporting)**: classified pressure ulcers according to the EPUAP classification system

	• **Definition (including ulcer stage)**: number of patients who developed a new pressure ulcer of stage 1 or worse (overall, and by stages) • **Dropouts**: 125 in foam 1 and 127 in foam 2 missed • **Notes (e.g. other results reported)**: 22 of 53 in foam 1 (including 12 Stage 1; 9 Stage 2; 1 Stage 3); 23 of 52 in foam 2 (including 16 Stage 1; 7 Stage 2; 0 Stage 3) *Time to pressure ulcer incidence* • **Reporting**: partially reported • **Notes**: this outcome is not systematically measured. "For patients who developed PUs, the median time to development of the first PU was 4 days and ranged from 1 to 15 days" *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was performed through an independent, secure, 24-hour randomization automated telephone system, ensuring allocation concealment. We used minimization so that groups were parallel" Comment: low risk of bias due to the use of a proper randomisation method.
Allocation concealment (selection bias)	Low risk	Quote: "Randomization was performed through an independent, secure, 24-hour randomization automated telephone system, ensuring allocation concealment" Comment: low risk of bias due to the proper concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "Skin follow-up evaluations were completed daily" Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	***Outcome group: all*** Comment: high risk of bias because "FIGURE. Flow of patients through the trial" shows that of 357 individuals who were randomised, only 105 are included in analysis
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Park 2017

Study characteristics	
Methods	**Study objective**: to compare a viscoelastic foam overlay (VEFO) to a standard hospital mattress for pressure injury (PI) prevention **Study design:** randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 2 weeks **Number of arms:** 2 **Single centre or multi-sites:** single centre **Study start date and end date**: data collected from October 2013 to November 2014 **Setting**: hospital (Samsung Medical Center)
Participants	**Baseline characteristics** **Inclusion criteria**: adults 19 years or older with intact skin (no stage 1 or other PIs or incontinence-associated dermatitis (IAD)), a Braden Scale score of 16 or less (this cutoff point was selected because it indicates moderate PI risk and the need for more aggressive PI preventive interventions than those used for any inpatient), and body weight less than 100 kg according to the policy of the manufacturer of the VEFO tested in this study. **Exclusion criteria**: not reported **Sex (M:F)**: 65:45 overall; 31:24 in VEFO and 34:21 in control **Age (years)**: mean 69.56 (SD 14.26) in VEFO, 64.15 (18.38) in control **Baseline skin status**: mean Braden score 14.71 (SD 1.60) in VEFO and 14.33 (2.01) in control; all at risk, no existing ulcers **Group difference**: no difference **Total number of participants:** n = 122; 110 analysed **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Viscoelastic foam overlay (VEFO) • **Description of interventions**: viscoelastic polyurethane polyester foam overlay (Viscosafe Overlay Yellow/Pink 111-45; Safe4Care ApS, Soro, Denmark), placed on top of our standard hospital mattress ... its indentation hardness was 40%, its length was 191 cm, and its width was 90 cm. The core was an open-cell foam with characteristic viscosity and elasticity of 3 cm, respectively. The outer cover of the VEFO is also made of an elastic polyester material designed to be waterproof, breathable and reduce friction. • **NPIAP S3I classification**: non-powered, reactive foam surface • **Co-interventions**: standard ulcer prevention care bundle including turning and repositioning • **Number of participants randomised**: n = 59 • **Number of participants analysed**: n = 55 Standard hospital mattress • **Description of interventions**: had a height of 6 cm and a regenerated compressed sponge with a 4- to 5-fold stronger compressive force than that of a general sponge; the mattress is covered with a polyvinyl chloride material

	• **NPIAP S3I classification**: standard hospital surface • **Co-interventions**: standard ulcer prevention care bundle including turning and repositioning • **Number of participants randomised**: n = 63 • **Number of participants analysed**: n = 55
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 2 weeks • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: determined using the staging system described in guidelines from the NPIAP, EPUAP, and PPPIA 2014 • **Definition (including ulcer stage)**: incidence of ulcers of any stages • **Dropouts**: 4 of 59 in VEFO and 8 of 63 in control • **Notes (e.g. other results reported)**: 2 of 55 (3.6%) in VEFO (1 Stage 1 and 1 Stage 2) vs. 15 of 55 (27.3%) in control (7 Stage 1, 7 Stage 2 and 1 Stage 3); Chi^2 11.75, P = 0.001 *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported **Outcomes that are not considered in this review but reported in trials**: • Interface pressure outcome
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Participants were randomly allocated to groups using a 1:1 allocation generated via a computer-based program" Comment: low risk of bias because of the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "We enrolled 122 subjects; 59 were randomly allocated to the experimental group and 63 to the control group ... the final sample comprised 110 subjects; 55 were allocated to the experimental group and 55 in the control group" Quote: "5 subjects transferred to different nursing units during data collection, 3 were found to have PI, IAD, or other skin diseases during the study ..." Comment: high risk of bias because even though the overall dropout rate (9.8%) is not high, some missed participants had incident pressure ulcers during the study.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Rosenthal 2003

Study characteristics	
Methods	**Study objective**: to compare the rate of healing when patients are treated with low-air-loss (LAL) bed, pressure-relieving bed overlays, and generic total contact seat surface **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 6 months **Number of arms**: 2 (of 3 arms) considered eligible for inclusion **Single centre or multi-sites**: multiple sites **Study start date and end date**: not described **Setting**: long-term care facilities, and community nursing homes
Participants	**Baseline characteristics** **Inclusion criteria**: those being alert, able to sit in the 6 months before the study, still sit up with assistance, with a stage III or IV ulcer on the coccyx, trochanter, or ischial tuberosities **Exclusion criteria**: those with sacral pressure ulcers; previously in a trial to treat their current pressure ulcer; already on low-air-loss, or transfer to low-air-loss planned; skin grafting planned within 1 week; with an active sinus tract or fistula; poor nutrition; requiring antibiotics to treat methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Enterococci*, or active skin infection; osteomyelitis diagnosed; body weight below 60 kg; unable to flex both hip and knee at least 90 degree **Sex (M:F)**: not given **Age (years)**: mean 69.0 (SD 4.1) in LAL bed and 68.6 (3.0) in overlay **Baseline skin status**: all with grade III or IV ulcer **Group difference**: no difference **Total number of participants**: n = 76 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals

Interventions	**Intervention characteristics** Low-air-loss (LAL) bed • **Description of interventions**: low-air-loss suspension bed (TheraPulse bed) attaching a rack of inflatable fabric pillows to a modified bed frame to provide pulsating air support intended to increase capillary blood flow and to lower interface pressure. These beds are covered with the manufacturer's Gore-Tex fabric surface to reduce friction. • **NPIAP S3I classification:** powered, alternating pressure (active), low air loss air surface • **Co-interventions**: turning every 2 hours • **Number of participants randomised**: n = 38 • **Number of participants analysed**: Bed overlay • **Description of interventions**: a pressure-reducing advanced medium density open-cell polyurethane foam overlay that was contour cut from 8.89 cm (3.5 inches) solid foam. Each Geo-Matt cell was meant to respond individually to the weight put on it, thereby customising support to minimize pressure and shear. Additional source of information is from http://www.spanamerica.com/ultramax.php • **NPIAP S3I classification**: non-powered, reactive foam surface • **Co-interventions**: turning every 2 hours • **Number of participants randomised**: n = 38 • **Number of participants analysed**:
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 6 months • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not given • **Definition (including ulcer stage)**: not given • **Dropouts**: 1 death excluded; 3 participants withdrawn at 4 weeks due to worsened condition, all in overlay group • **Notes (e.g. other results reported)**: no new pressure ulcers were found in either arm *Time to pressure ulcer incidence* • **Not reported** *Support-surface-associated patient comfort* • **Not reported** *All reported adverse events using allocated support surfaces* • **Notes**: 1 death in this study but the authors did not specify which group the death was in; 3 participants withdrawn at 4 weeks due to worsened condition, all in overlay group *Health-related quality of life (HRQOL)* • **Not reported** *Cost-effectiveness* • **Not reported**

	Outcomes that are not considered in this review but reported in trials: • Ulcer healing • Time to ulcer healing
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was performed by placing a number corresponding to each experimental condition into a sealed envelope with an equal number of envelopes per condition. A research assistant with no clinical experience drew envelopes by lot as eligible subjects were identified" Comment: low risk of bias because the sequence generation process seems proper.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: unclear risk of bias because the dropout rate is low but unbalanced (1 death was excluded from analysis and it was unclear which group the death was in; 3 participants withdrawn at 4 weeks due to worsened condition, all in overlay group).
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Russell 2003a

Study characteristics

Methods	**Study objective**: to determine whether a viscoelastic polymer (energy absorbing) foam mattress was superior to a standard hospital mattress for pressure ulcer prevention and to analyse the cost-effectiveness in comparison with standard hospital mattresses. **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: median days 11 (25th to 75th percentile 6 to 20) in CONFORM-Med; 12 (7 to 22) in standard mattress **Number of arms**: 2 **Single centre or multi-sites**: multi-sites **Study start date and end date**: May 1999 to June 2000 **Setting**: elderly acute care, rehabilitation, and orthopedic wards of hospitals.

Participants	**Baseline characteristics** **Inclusion criteria**: all patients admitted to acute elderly care and orthopedic wards at hospital 1; elderly rehabilitation wards at hospital 2; and acute elderly care wards at hospital 3 within the preceding 72 hours, who are aged 65 years and older; a pressure ulcer (PrU) risk of 15 to 20 on the Waterlow score, which is based on physiologic, demographic, and disease-specific features; consent to regular examination of pressure areas **Exclusion criteria**: obesity (> 341 lb [> 155 kg]); previous trial participation; refusal of consent **Sex (M:F)**: 391:777 across groups **Age (years)**: median 83 (25th to 75th percentile: 79 to 87) **Baseline skin status**: mean Waterlow 17.07 (SD 1.76) in CONFOR-Med; 16.98 (1.75) in standard mattress **Group difference**: no difference **Total number of participants**: 1168 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** CONFOR-Med mattress/cushion combination • **Description of interventions**: CONFOR-Med mattress/cushion combination (Aearo Company, Indianapolis, IN) constructed from a 3-inch layer of viscoelastic foam and a 3-inch layer of standard polyurethane foam. Viscoelastic (energy absorbing) polymer foam mattresses ... constructed of a single foam density or several foams of different densities in layers of progressively less deformable foam, down to a standard, resilience cushioning polyurethane foam base. The foam surface molds to the patient's body shape and, by reducing high-pressure zones ... • **NPIAP S3I classification**: non-powered, reactive foam surface; multi-layered, viscoelastic and polyurethane foam mattress • **Co-interventions**: not described • **Number of participants randomised**: n = 564 • **Number of participants analysed**: n = 562 Standard mattress/cushion combination • **Description of interventions**: King's Fund, Linknurse, Softfoam, or Transfoam, or a King's Fund mattress with a Spenco or Propad mattress overlay • **NPIAP S3I classification**: standard hospital surfaces • **Co-interventions**: not described • **Number of participants randomised**: n = 604 • **Number of participants analysed**: n = 604
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not specified • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: • **Definition (including ulcer stage)**: development of non-blanching erythema or worse, graded using the Torrance scale (blanching erythema = a Torrance grade I ulcer, and non-blanching erythema = a Torrance grade II ulcer)

- **Dropouts**: 2 excluded from CONFOR-Med
- **Notes (e.g. other results reported)**: 48 of 562 in CONFOR-Med; 66 of 604 in standard mattress. The authors also reported subgroup analysis by whether patients had blanching erythema on admission. These data not extracted.

Time to pressure ulcer incidence

- **Outcome type**: time-to-event
- **Time points**: not specified
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: see above
- **Definition (including ulcer stage)**: the number of participants who had not developed an ulcer divided by the total number of participants for each trial day
- **Dropouts**: see above
- **Notes**: figure 2a, 2b reported; HR 0.85 (95% CI 0.55 to 1.31) estimated by the review authors by using methods described in Tierney 2007

Support-surface-associated patient comfort

- **Outcome type**: continuous
- **Time points**: not specified
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: self-reported, using a 10-point comfort questionnaire (1 = completely relaxed, 10 = unbearable pain)
- **Definition**: the comfort of the mattresses
- **Dropouts**: "Of 1168 participants, 706 expressed opinions regarding comfort"
- **Notes**: no significant differences in comfort assessment were found. The average assessment of comfort for both mattress types ... with levels of 2.33 ± 0.98 and 2.46 ± 1.0 (P = NS) on a 1 to 10 scale.

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Outcome type**: continuous
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: 2 cost-effectiveness ratios were calculated: (1) a cost per any PrU avoided; and (2) a cost per non-blanching erythema (or worse) avoided. A cost-effectiveness acceptability curve was also generated.
- **Definition**: cost-effectiveness acceptability curve plots the probability of the cost-effectiveness of the new mattress against a range of cost-effectiveness ratios.
- **Notes**: an approximately 88% chance that the experimental equipment is the dominant option (i.e. more effective and less costly) ... a 95% chance that the experimental equipment produces a cost per averted non-blanching erythema area of GBP 100 (i.e. USD 140) or less (see Figure 3).

Outcomes that are not considered in this review but reported in trials:

	• Development of blanching erythema • Length of time spent on secondary equipment • Nursing intervention
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "On admission, participants were randomised to the standard equipment group or the experimental equipment group" Quote: "Equipment allocation at 2 sites was made by converting random numbers (Excel; Microsoft Corp, Redmond, WA) on a 50:50 basis ..." Comment: low risk of bias because study used a proper randomisation method.
Allocation concealment (selection bias)	Low risk	Quote: "At site 3, trial numbers were allocated sequentially and the patient chose from 1 of 2 opaque envelopes" Quote: "At sites 1 and 2, each trial ward kept sealed, opaque envelopes containing a trial number and equipment allocation" Quote: "All patients were enrolled into the trial by a research nurse, who carried out the randomization by taking an envelope" Comment: low risk of bias because a proper concealment was likely used.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "Because ... the experimental mattress surface is distinctive, data collection could not be blinded" Quote:"Although ... it as impossible to blind the research nurses to mattress assignment" Comment: high risk of bias because it is unlikely participants and personnel were blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "The participants' pressure areas were assessed daily by ward nurses ... A research nurse was immediately notified of any significant deterioration ... completed data collection proformas weekly" Quote: "Because the data collection team examined participants at bedside and the experimental mattress surface is distinctive, data collection could not be blinded" Comment: high risk of bias because outcome assessment was not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: primary outcome*** Quote: "The primary analysis was intention-to-treat and involved all randomised participants other than the 2 excluded participants" Comment: low risk of bias because ITT analysis is done.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Santy 1994

Study characteristics

Methods	**Study objective**: to evaluate the effect of 6 types of hospital mattress on the development of pressure damage **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 12 days **Number of arms**: 6 (of which 1 arm - Omnifoam - has no data available for analysis) **Single centre or multi-sites**: single centre **Study start date and end date**: started April 1993 **Setting**: orthopaedic trauma wards at Hull Royal Infirmary
Participants	**Baseline characteristics** **Inclusion criteria**: elderly patients (aged > 55 y) with hip fracture, with or without pressure ulcers **Exclusion criteria**: those with a pressure ulcer of grade 3 or 4 at entry **Sex (M:F)**: not reported **Age (years)**: estimated overall 80.24; mean 80.37 in Clinifloat; 79.09 in NHS contract; 81.57 in Transfoam; 78.86 in Therarest; 80.41 in Vaperm **Baseline skin status**: estimated overall 25.16; mean Waterlow 25.07 in Clinifloat; 24.27 in NHS contract; 25.80 in Transfoam; 24.76 in Therarest; 25.32 in Vaperm; some having Stage 1 and 2 pressure damage **Group difference**: no difference **Total number of participants**: n = 552 available **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Clinifloat • **Description of interventions**: Clinifloat (SSI Medical Sevices Ltd) consisting of deep cut foam cubes and evenly distributing patient's weight. • **NPIAP S3I classification**: non-powered, reactive foam surface • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 87 Omnifoam • **Description of interventions**: Omnifoam (Huntleigh Nesbit Evans Healthcare) made of a high quality multilayer foam construction, ventilated high density foam • **NPIAP S3I classification**: non-powered, reactive foam surface; high specification (high density) foam • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: no data for analysis; this arm was removed for this review Transfoam • **Description of interventions**: Transfoam (Karomed Ltd) constructed of layered polyurethane foam (150 mm thick), made from a foam density of 30-33 kg/m^3 and hardness 145-170 N • **NPIAP S3I classification**: non-powered, reactive foam surface; high

	specification (density of 30 to 33 kg/m^3 and hardness 145 to 170 N) foam • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 136 Therarest • **Description of interventions**: Therarest (KCI Therapeutic Services) with 3 layer therapeutic fire retardant foam core, absorbing and dispersing pressure from high pressure points • **NPIAP S3I classification**: non-powered, reactive foam surface • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 102 Vaperm • **Description of interventions**: Vaperm (Huntleigh Nesbit Evans Healthcare) constructed from 4 layers of foam increasing in density from 35 kg/m^3 at the top to 60 kg/m^3 at the bottom with the inner core of high density ventilated foam • **NPIAP S3I classification**: non-powered, reactive foam surface; high specification (density of 35 kg/m^3 to 60 kg/m^3) foam • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 116 NHS Contract (150 mm) (Reylon Ltd) • **Description of interventions**: NHS Contract (150 mm) (Reylon Ltd) made of a single block of combustion modified, high resilience polyether foam with a density of 39 to 42 kg/m^3 and hardness index of 170 N (130 mm thickness) • **NPIAP S3I classification**: non-powered, reactive foam surface; high specification (density of 39 to 42 kg/m^3 and hardness index of 170 N) foam • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 64
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: defined by Torrance criteria • **Definition (including ulcer stage)**: the need for the patient to be removed from the mattress due to skin deterioration or developing a Stage 3 ulcer. This is not a directly relevant outcome. • **Dropouts**: not described • **Notes (e.g. other results reported)**: 8 of 87 cases removed (9.19%) in Clinifloat; 17 of 64 (26.56%) in NHS Contract; 14 of 136 (10.29%) in Transfoam; 11 of 102 (10.78%) in Therarest; 9 of 116 (7.75%) in Vaperm

	Time to pressure ulcer incidence • Not reported *Support-surface-associated patient comfort* • Not reported *All reported adverse events using allocated support surfaces* • Not reported *Health-related quality of life (HRQOL)* • Not reported *Cost-effectiveness* • Not reported **Outcomes that are not considered in this review but reported in trials**: • Price of mattresses
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Mattresses were randomly allocated to patients using random number tables" Comment: low risk of bias because a proper randomisation method was applied.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: ulcer incidence*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: ulcer incidence*** Comment: skin assessment by a research nurse but no information as to whether they were blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	***Outcome group: ulcer incidence*** Comment: no information provided.
Selective reporting (reporting bias)	High risk	Comment: 6 types of mattresses were evaluated initially; however, the data collected on the Omnifoam mattress were not analysed because there were insufficient numbers for the results to be significant and they could possibly adversely affect the analysis.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Sauvage 2017

Study characteristics	
Methods	**Study objective**: to compare Axtair One, an alternating pressure air mattress (APAM), with a viscoelastic foam mattress (VFM) in elderly patients at moderate to high risk of developing pressure ulcers (PUs) **Study design:** randomised controlled trial **Study grouping**: parallel group

	Duration of follow-up: 30 days **Number of arms:** 2 **Single centre or multi-sites:** multi-sites **Study start date and end date**: February 2012 to March 2015 **Setting:** medium- and long-term stay facilities
Participants	**Baseline characteristics** **Inclusion criteria**: males and females aged 70 and over, bedridden for at least 15 hours per day, with reduced mobility due to medical problems (such as malnutrition, low blood pressure, urinary incontinence, neurological diseases and sensory disorders), a low to zero positioning capability, a Karnofsky score ≤ 40% and a planned period of hospitalisation of at least 2 weeks. Had no PUs at the time of enrolment but had a medium to high risk for developing PUs, as defined by a Braden score ≤ 14. **Exclusion criteria**: a weight > 120kg, body mass index (BMI) < 12kg/m^2, a nutritional status score < 12 according to the Mini Nutritional Assessment (MNA), uncompensated nutritional insufficiency and ongoing participation, or within 15 days before, in another clinical research study **Sex (M:F)**: 13:26 in APAM; 9:28 in VFM **Age (years)**: mean 86.03 (SD 5.49) in APAM, 84.59 (6.68) in VFM **Baseline skin status**: mean Braden score 11.77 (SD 1.27) in APAM, 12.08 (1.26) in VFM; all intact skin **Group difference**: no difference **Total number of participants:** n = 76 **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Alternating pressure air mattress (APAM) • **Description of interventions**: APAM (Axtair One, Asklé Santé, Nîmes, France) consisted of therapeutic air cells with a height of 12 cm, supplied by a compressor, which adjusts the pressure based on the patient's weight and whose mode of operation allows alternating inflation of 1 out of 2 cells, with a 6 minute cycle time. • **NPIAP S3I classification:** powered, alternating pressure (active) air surface • **Co-interventions**: not reported • **Number of participants randomised**: n = 39 • **Number of participants analysed**: n = 39 Viscoelastic foam mattress (VFM) • **Description of interventions**: VFM (ALOVA mattress, Asklé Santé, Nîmes, France) was composed of a base made of high resilience foam (density > 34 kg/m^3) and an upper layer of viscoelastic foam (density > 75kg/m^3). • **NPIAP S3I classification**: non-powered, reactive foam surface; high specification foam (2 layered; base layer of high resilience foam, density > 34kg/m^3; upper layer of viscoelastic foam, density > 75kg/m^3). • **Co-interventions**: not reported • **Number of participants randomised**: n = 37 • **Number of participants analysed**: n = 37

Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 30 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not reported • **Definition (including ulcer stage)**: incidence of pressure ulcers of any stage • **Dropouts**: intention-to-treat (ITT) analysis performed • **Notes (e.g. other results reported)**: 2 of 39 participants in APAM (1 category I ulcer and 1 category II ulcer); 13 of 37 participants in VFM (7 category I ulcers, 5 category II ulcers and 1 category III ulcer). *Time to pressure ulcer incidence* • **Outcome type**: binary • **Time points**: 30 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not reported • **Definition (including ulcer stage)**: time to appearance of ulcers • **Dropouts**: censoring • **Notes (e.g. other results reported)**: the cumulative risk of PUs was estimated at 6.46% (95% confidence interval (CI) 1.64 to 23.66) in the APAM group and at 38.91% (95% CI 24.66 to 57.59) in the VFM group, P = 0.001 (logrank test). Kaplan-Meier curves presented in Fig 2 and HR 0.18 (95% CI 0.07 to 0.50) estimated by the review authors by using methods described in Tierney 2007. *Support-surface-associated patient comfort* • **Outcome type**: binary • **Time points**: day 8, day 15, day 22, and day 30 • **Reporting:** fully reported • **Measurement method (e.g. scale, self-reporting)**: perception of patient comfort collected on days 8, 15, 22 and 30 via a satisfaction questionnaire (skin-mattress contact, feeling of warmth, discomfort due to motor noise and disturbed sleep) • **Definition (including ulcer stage)**: comfort rates • **Dropouts**: 3 of 39 APAM vs 6 of 37 VFM at ***day 8*** ; 6 of 39 APAM vs 10 of 37 VFM at ***day 15*** ; 11 of 39 vs 16 of 37 at ***day 22*** ; 15 of 39 APAM vs 20 of 37 VFM at ***day 30***. • **Notes**: data presented by subscales of the measurement tool and not extracted for this review. Difference in satisfaction between the 2 groups not significant, P = 0.21 *All reported adverse events using allocated support surfaces* • **Notes**: the serious adverse events (SAEs) reported in the APAM group were 2 deaths, a massive septic shock with acute pulmonary oedema and a decompensation of an insulin-dependent diabetes. No SAE was reported in the VFM group. There were 20 adverse events reported in each group, including 2 discomforts in the APAM group and one hyperalgesia in the VFM group. The other events did not involve the mattresses. *Health-related quality of life (HRQOL)* • **Reporting**: not reported

	Cost-effectiveness • **Reporting**: not reported **Outcomes that are not considered in this review but reported in trials**: • The duration of bed rest • The duration of sitting in a chair • The frequency of preventative interventions • Any therapeutic change
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was centralised (RANDLIST software v1.2) and globally balanced intracentre with random block sizes established from two possibilities (2 and 4)" Comment: low risk of bias because of the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Quote: "Randomisation was centralised (RANDLIST software v1.2) and globally balanced intracentre with random block sizes established from two possibilities (2 and 4)" Comment: unclear risk of bias because even though central randomisation was performed, the small block size means that the allocation in the subsequent block is predictable if a prior randomisation sequence has already been known.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "This randomised, controlled, superiority, parallel-group, open-label, multicentre ..." Quote: "PUs preventive care had to be performed in compliance with validated care protocols compliant with Good Professional Practice Recommendations" Comment: high risk of bias because open label is clearly stated. Additionally, it is unknown if performance between groups might be unbiased even though there seems to be a standardised care plan.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "This randomised, controlled, superiority, parallel-group, open-label, multicentre ..." Comment: high risk of bias because open label is clearly stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "The population selected for the main analysis were all randomised patients in intention-to-treat (ITT)." Comment: low risk of bias because ITT analysis was performed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Schultz 1999

Study characteristics	
Methods	**Study objective**: to evaluate a special operating room (OR) mattress overlay in preventing pressure ulcer development **Study design**: randomised controlled trial **Study grouping**: parallel group

	Duration of follow-up: 6 days after surgeries **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: operating room (hospital)
Participants	**Baseline characteristics** **Inclusion criteria**: patients scheduled for inpatient care, 18 years of age or older, with surgery scheduled to last longer than 2 hours in the lithotomy or supine position **Exclusion criteria**: patients with an existing pressure ulcer, patients with severe chronic skin problems, or patients receiving only local anaesthesia **Sex (M:F)**: 133:73 in experimental; 133:74 in control **Age (years)**: mean 65.68 (SD 11.66) in experimental; 65.73 (12.87) in control **Baseline skin status**: mean Braden 22.15 (SD 1.98) in experimental; 22.41 (1.34) in control; free of existing ulcers **Group difference**: no difference **Total number of participants**: n = 413 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** New mattress overlay • **Description of interventions**: the special mattress overlay, ... made of foam with a 25% indentation load deflection (ILD) of 30 pounds and a density of 1.3 • **NPIAP S3I classification**: non-powered, reactive foam surface; density 20.8 kg/m^3, 25% ILD of 30 pounds • **Co-interventions**: all open heart surgery patients had gel pads placed under their buttocks • **Number of participants randomised**: n = 206 • **Number of participants analysed**: n = 206 Usual perioperative care/standard surgical care • **Description of interventions**: patients in the control or "usual care" group were padded, based on the discretion of the individual nurse. Padding options included gel pads, foam egg crate mattresses, and foam donuts for the heels and elbows. • **NPIAP S3I classification**: standard hospital surface • **Co-interventions**: all open heart surgery patients had gel pads placed under their buttocks • **Number of participants randomised**: n = 207 • **Number of participants analysed**: n = 207
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 6 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: using the pressure ulcer classification system that is equivalent to NPIAP/EPUAP system

	• **Definition (including ulcer stage)**: the number of subjects developing ulcers of stage I or higher • **Dropouts**: not described, probably no missing • **Notes (e.g. other results reported)**: 55 of 206 individuals having ulcers of stage I or higher in experimental (6 stage II and 49 stage I); 34 of 207 in control (3 stage II and 31 stage I) *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported **Outcomes that are not considered in this review but reported in trials**: • Risk factors of ulcer development analysed but not extracted
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Again, using a random number table, patients were then assigned to the control or the experimental group by a principal investigator" Comment: low risk of bias due to the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcome (primary outcome)*** Quote: "... the study group designation was blinded to all nursing personnel" Comment: unclear because no information provided on participants' blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: all outcome (primary outcome)*** Quote: "Beginning on the day after surgery and continuing for six days, two research assistants, blinded to the study group of the patient, examined the skin over the bony prominences of each patient for any evidence of skin changes" Comment: low risk of bias because outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes (primary outcome)*** Comment: no attrition.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Stapleton 1986

Study characteristics	
Methods	**Study objective**: not provided **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: not described **Number of arms**: 3 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: acute care setting
Participants	**Baseline characteristics** **Inclusion criteria**: female elderly patients with fractured neck of femur, without existing pressure ulcers, Norton score 14 or less **Exclusion criteria**: patients not meeting the criteria, or admitted with existing pressure sores **Sex (M:F)**: all female patients (0:32 in large cell Ripple; 0:34 in polyether foam pad; 0:34 in Spenco pad) **Age (years)**: mean 81 across groups **Baseline skin status**: mean Norton score 12.0 in large cell Ripple; 12.8 in polyether foam pad; 12.9 in Spenco pad; no existing pressure ulcers **Group difference**: no difference **Total number of participants**: n = 100 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Large Cell Ripple (Talley) • **Description of interventions**: Large Cell Ripple (Talley) • **NPIAP S3I classification:** powered, alternating pressure (active) air surface • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 32 Polyether foam pad • **Description of interventions**: polyether foam pad 2 feet x 2 feet x 3-inch thickness • **NPIAP S3I classification**: non-powered, reactive foam surface • **Co-interventions**: not described • **Number of participants randomised**: not described • **Number of participants analysed**: n = 34 Spenco pad • **Description of interventions**: Spenco pad • **NPIAP S3I classification**: non-powered, reactive fibre surface • **Co-interventions**: not described • **Number of participants randomised**: not described

	• **Number of participants analysed**: n = 34
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not reported • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: graded by Borders (Grade A superficial/blister; Grade B a break in skin but no crater; Grade C a break in skin with crater; Grade D blackened tissue) • **Definition (including ulcer stage)**: patients with the development of pressure ulcers graded by Borders • **Dropouts**: not described • **Notes (e.g. other results reported)**: 12 of 34 in Spenco (2 Grade A/ 8 Grade B/ 2 Grade C/ 0 Grade D); 14 of 34 in Foam (1/5/3/5); 11 of 32 in Ripple (2/9/0/0) *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: “patients for the first two groups were selected by lottery, and thereafter patients were allocated to each group systematically, in rotation” Comment: unclear risk of bias because it is unclear if a proper randomisation method was applied.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: no information provided.
Selective reporting (reporting bias)	Unclear risk	Comment: no information provided.

Other bias	Unclear risk	Comment: no information provided.

Takala 1996

Study characteristics	
Methods	**Study objective**: to test the hypothesis that this device [a new, easily adjustable anti-decubitus mattress] would be clinically effective in the prevention of pressure sores in patients requiring prolonged intensive care **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 14 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: intensive care unit (hospital)
Participants	**Baseline characteristics** **Inclusion criteria**: non-trauma patients admitted to intensive care unit (ICU) expected to stay > 5 days **Exclusion criteria**: patients with accidental injuries **Sex (M:F)**: 12:9 in Carital Optima; 13:6 in standard hospital foam mattress **Age (years)**: mean 60 (SD 16) in Carital Optima; 63 (12) in standard hospital foam mattress **Baseline skin status**: Norton below 8 across groups (high risk) **Group difference**: no difference **Total number of participants**: n = 40 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Pressure-relieving mattress • **Description of interventions**: pressure-relieving mattress (Carital Optima, Carital Ltd, Tuusula, Finland). Carital Optima, constant low pressure mattress comprising 21 double air bags on a base, reduce the pressure on the skin by distributing the patient's weight over a maximum contact area. Formed of the separate upper layer of the cells ... pressure within the upper layer of cells and in the three compartments of the lower layer of cells can be adjusted separately (Takala 1996). Additional source of information from Carital-Optima-Brochure-1.pdf (directhealthcaregroup.com) indicates that Carital Optima needs electricity to be functional • **NPIAP S3I classification:** powered, reactive air surface • **Co-interventions**: not described • **Number of participants randomised**: n = 21 • **Number of participants analysed**: n = 21 Standard hospital mattress • **Description of interventions**: standard hospital mattress (10-centimetre thick foam mattress, density 35 kg/m^3, Espe Inc, Kouvola, Finland). • **NPIAP S3I classification**: non-powered, reactive foam surface; high specification (density 35 kg/m^3) foam • **Co-interventions**: not described

	• **Number of participants randomised**: n = 19 • **Number of participants analysed**: n = 19
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 14 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: graded by Shea criteria • **Definition (including ulcer stage)**: the development of pressure ulcers graded by Shea criteria • **Dropouts**: intention-to-treat (ITT) analysis • **Notes (e.g. other results reported)**: 0 of 21 in pressure-relieving mattress; 7 of 19 in standard hospital mattress (with a totality of 13 ulcers: 9 Shea grade 1A; 4 grade 1B) *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported **Outcomes that are not considered in this review but reported in trials**: • Interface pressure
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Those with an expected ICU stay exceeding five days were randomly assigned to be treated on either ..." Comment: unclear risk of bias because a proper randomisation criteria is unspecified.
Allocation concealment (selection bias)	High risk	Comment: randomisation influenced by mattress availability; therefore, allocation not concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: pressure ulcer outcome*** Quote: “The study was not blinded, since the severity of illness of the patients precluded their transfer for evaluation of the skin condition by a blinded reviewer, and the type of mattress in the bed could not be blinded” Comment: high risk of bias because this statement implies blinding of participants and personnel was likely impossible.
Blinding of outcome assessment (detection bias)	High risk	***Outcome group: pressure ulcer outcome*** Quote: “The study was not blinded, since the severity of illness of the patients precluded their transfer for evaluation of the skin

All outcomes		condition by a blinded reviewer, and the type of mattress in the bed could not be blinded" Comment: high risk of bias as it is clearly stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: pressure ulcer outcome*** Quote: "Sequential analysis of the primary outcome variable (pressure sore formation) on an intention-to-treat basis was done after each block of four patients had completed the treatment" Comment: low risk of bias because ITT analysis was conducted.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Van Leen 2011

Study characteristics	
Methods	**Study objective**: to evaluate the clinical efficacy of combining a standard 15 cm cold foam mattress with a static air overlay mattress versus a cold foam mattress alone in preventing pressure ulcers **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 6 months **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: March 2002 and October 2004 **Setting**: nursing home
Participants	**Baseline characteristics** **Inclusion criteria**: age > 65, a Norton score between 5 and 12 and informed consent of the patients or their representatives in case of mental disorders **Exclusion criteria**: a pressure ulcer in the previous 6 months **Sex (M:F)**: 9:33 in static air; 7:34 in cold foam **Age (years)**: mean 81.1 (SD 8.37) in static air; 83.1 (7.86) in cold foam **Baseline skin status**: Norton score presented by subgroups; Norton scale score lower than 12 (lower than 14 = at risk for pressure ulcers) and no existing ulcers **Group difference**: more patients in static air having a very low Norton score (i.e. more pressure ulcer-prone patients) **Total number of participants**: n = 83 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Cold foam mattress • **Description of interventions**: standard 15 cm cold foam mattress • **NPIAP S3I classification**: non-powered, reactive foam surface • **Co-interventions**: standardised the pressure reduction in sitting position by using a static air cushion • **Number of participants randomised**: n = 42 • **Number of participants analysed**: n = 42

	Static air overlay • **Description of interventions**: a combination of standard 15 cm cold foam mattress with static air overlay • **NPIAP S3I classification**: non-powered, reactive air surface • **Co-interventions**: standardised the pressure reduction in sitting position by using a static air cushion • **Number of participants randomised**: n = 41 • **Number of participants analysed**: n = 41
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not specified • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: pressure ulcers classified by using EPUAP system • **Definition (including ulcer stage)**: the number of individuals developing a pressure ulcer grade 2, 3 and 4 at the heel or in the sacral/hip region • **Dropouts**: not described • **Notes (e.g. other results reported)**: 2 of 41 in static air mattress (1 Grade 2 and 1 Grade 3); 7 of 42 in cold foam mattress (2 Grade 2; and 5 Grade 3) *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported **Outcomes that are not considered in this review but reported in trials**: • Treatment data on the new ulcers reported but not extracted
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization into two groups was performed after informed consent using numbered envelopes" Comment: unclear risk of bias because the randomisation method used is not sufficiently clear.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes (primary outcome)*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: all outcomes (primary outcome)*** Quote: "A weekly inspection of the skin to assess the possible occurrence of a skin lesion was done by an independent nurse" Comment: low risk of bias because the attempt was made to blind outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes (primary outcome)*** Comment: no attrition identified.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Van Leen 2013

Study characteristics	
Methods	**Study objective**: to evaluate the clinical efficacy of a combination of a standard 15 cm viscoelastic foam mattress with a static air overlay mattress vs a standard 15 cm viscoelastic foam mattress alone in preventing pressure ulcers **Study design**: randomised controlled trial **Study grouping**: cross over design (data at the first stage extracted) **Duration of follow-up**: 6 months **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: nursing home
Participants	**Baseline characteristics** **Inclusion criteria**: age > 65, a Braden score between 6 and 19, and informed consent of the patients or their representatives in case of dementia or other mental disorder **Exclusion criteria**: patients with an existing pressure ulcer **Sex (M:F)**: 14:6 in static air; 18:3 in foam **Age (years)**: mean 79.1 (no SD) in static air; 80.8 in foam **Baseline skin status**: at risk and without existing ulcers. Braden scores classified into 2 subgroups and reported accordingly; not extracted **Group difference**: no difference **Total number of participants**: n = 41 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Standard viscoelastic foam mattress • **Description of interventions**: standard viscoelastic foam mattress • **NPIAP S3I classification**: non-powered, reactive foam surface; viscoelastic foam

	• **Co-interventions**: when out of bed, all patients sat on a static air pillow • **Number of participants randomised**: n = 20 • **Number of participants analysed**: n = 20 Static air overlay • **Description of interventions**: a combination of a standard visco-elastic foam mattress with a static air overlay • **NPIAP S3I classification**: non-powered, reactive air surface • **Co-interventions**: when out of bed, all patients sat on a static air pillow • **Number of participants randomised**: n = 21 • **Number of participants analysed**: n = 21
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 6 months • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not reported; probably measured by the primary investigator • **Definition (including ulcer stage)**: the development of category 2, 3, or 4 pressure ulcers (PUs) (EPUAP-classification) • **Dropouts**: no missing participants • **Notes (e.g. other results reported)**: 1 of 20 in static air; 3 of 21 in foam *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported **Outcomes that are not considered in this review but reported in trials**: • Treatment data on the new ulcers reported but not extracted
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomised into 2 groups using numbered envelopes" Comment: low risk of bias because, although the randomisation method is not sufficiently presented in the paper, author response suggests remote computer randomisation sequence generation.

Allocation concealment (selection bias)	Unclear risk	Comment: unclear risk of bias because author responded that sealed envelopes were opened by nurse but its unclear if envelopes were sequentially numbered and opaque.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes (primary outcome)*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: all outcomes (primary outcome)*** Quote: "Patients' skin was inspected weekly to assess the possible occurrence of a skin lesion" Comment: no information provided on the blinding of outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes (primary outcome)*** Comment: no attrition identified; 2 cases were transferred to low-air-loss bed treatments after they developed category III ulcers.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Van Leen 2018

Study characteristics	
Methods	**Study objective**: to test the pressure ulcer (PrU) preventive effect of this system [a pressure-relieving, shear stress-diminishing, and microclimate-controlling skin interface multilayer support system (Bedcare; Sense Textile, 's-Hertogenbosch, the Netherlands)] compared with a viscoelastic foam mattress alone **Study design:** randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 12 weeks of study period **Number of arms:** 2 **Single centre or multi-sites**: multi-sites **Study start date and end date**: not described **Setting**: nursing homes
Participants	**Baseline characteristics** **Inclusion criteria**: all residents at medium/high risk (Braden score < 16) of PrUs ... age older than 60 years, life expectancy greater than 3 months, and informed consent **Exclusion criteria**: a PrU in the last 3 months, participation in a comparable trial, or a physical and/or mental condition that could interfere with participation (such as sepsis, immune disease, palliative status) **Sex (M:F)**: 71.8% of 103 females in multilayer mattress; 69.9% of 103 females in viscoelastic foam **Age (years)**: 83.1 in multilayer mattress; 81.7 in viscoelastic foam **Baseline skin status**: Braden score 13.1 in multilayer mattress; 13.3 in viscoelastic foam; at risk but no existing ulcers **Group difference**: no difference **Total number of participants:** n = 206 **Unit of analysis:** individuals

	Unit of randomisation (per patient): individuals
Interventions	**Intervention characteristics** Multilayer mattress system • **Description of interventions**: received the same new high-quality viscoelastic foam mattress together with the new multilayer system (total thickness, 13 mm) (Bedcare; Sense Textile, 's-Hertogenbosch, the Netherlands), consisting of 3 separate layers, each with an independent function: 1. The Mini Overlay System (MOS; thickness, 9.5 mm), a 3-dimensional pressure-relieving spacer fabric ... 2. A textile mattress cover (made of polyester and elastan, covered with polyurethane; 0.5 mm) ... 3. Stay and Transfer Sheet (STS; thickness, 3 mm), a 3-dimensional knitted spacer fabric • **NPIAP S3I classification**: non-powered, reactive surface; undefined in NPIAP S3I • **Co-interventions**: when out of bed, all residents sat on a PrU-preventive air pillow • **Number of participants randomised**: n = 103 • **Number of participants analysed**: n = 103 Viscoelastic foam mattress • **Description of interventions**: high-quality viscoelastic foam mattress (Formafoam, Kabelfabriek Eupen, Belgium) • **NPIAP S3I classification**: non-powered, reactive foam surface; viscoelastic foam • **Co-interventions**: when out of bed, all residents sat on a PrU-preventive air pillow • **Number of participants randomised**: n = 103 • **Number of participants analysed**: n = 103
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not described • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not described in the paper but mentioned in trial register as "definitions Richtlijn preventie van decubitus V&VN 2009" • **Definition (including ulcer stage)**: the development of a category 2, 3, or 4 PrU according to definitions Richtlijn preventie van decubitus V&VN 2009 • **Dropouts**: none • **Notes (e.g. other results reported)**: 9 of 103 in multilayer mattress (3 category 2 on sacral, 3 category 2 on heel, 2 category 2 on others; 1 category 3 on heel and 1 category 3 on other); 5 patients of 103 in viscoelastic foam (2 category 2 on sacral, 3 category 2 on others; 3 category 3 on heel); P = 0.180 *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Notes**: no adverse events were reported during the study period

	Health-related quality of life (HRQOL) • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomization into 2 groups was performed by using the Castor randomization software (version 1.44; Mionix, Malmo¨ , Sweden)." Comment: low risk of bias because of the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Data were collected weekly, controlled by an independent research nurse." Comment: unclear risk of bias because of insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: low risk of bias because it appears to include all 206 patients in analysis.
Selective reporting (reporting bias)	High risk	Comment: high risk of bias because the study protocol is available from https://www.trialregister.nl/trial/4435 and it is clear that the pre-specified costs outcome is not presented.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Vyhlidal 1997

Study characteristics

Methods	**Study objective**: this study compares these 2 foam products [MAXIFLOAT foam mattresses and the Iris 3000 foam overlay] based on pressure ulcer incidence in an at-risk population **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 21 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: a 250-bed, teaching, skilled nursing facility (hospital-based facility)
Participants	**Baseline characteristics** **Inclusion criteria**: (a) newly admitted to the skilled nursing facility with an estimated stay of at least 10 days; (b) free of existing pressure ulcers; and (c) at-

	risk for pressure ulcer development (Braden Scale score < 18 with a subscale score of < 3 in sensory perception, mobility, or activity levels) **Exclusion criteria**: not described **Sex (M:F)**: 9:11 in each group **Age (years)**: mean 80.16 (SD 8.96) in Iris 3000; 74.25 (17.49) in MAXIFLOAT **Baseline skin status**: mean Braden scores 14.5 (SD 1.61) in the Iris 3000; 14.7 (2.28) in the MAXIFLOAT **Group difference**: people in the MAXIFLOAT group were significantly heavier (in terms of the body mass index) than those in the Iris 3000 group (t = 2.6, P = 0.013); the MAXIFLOAT group also stayed on the mattress longer (t,= 2.24, P = 0.03) **Total number of participants**: n = 40 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Iris 3000 • **Description of interventions**: the Iris 3000 is a 4-inch, 1.8-lb density foam overlay with a flat, dimpled surface • **NPIAP S3I classification**: non-powered, reactive foam surface; density of 28.8 kg/m^3 foam • **Co-interventions**: received standards of care • **Number of participants randomised**: n = 20 • **Number of participants analysed**: n = 20 MAXIFLOAT • **Description of interventions**: the MAXIFLOAT foam mattress is a replaceable-parts mattress ... (b) a 1½-inch thick, 2.4-lb dual IFD (indentation force load deflection), luxury-grade, high-resiliency, antimicrobial foam; (c) a centre core 29-lb IFD flame-retardant, polyurethane foam with exclusive precision die cuts and a 16-inch long by 26-inch wide non-removable polyester fibber heel pillow ... • **NPIAP S3I classification**: non-powered, reactive foam surface; high specification (high-resiliency, 29 lb IFD, polyurethane) foam. • **Co-interventions**: received standards of care • **Number of participants randomised**: n = 20 • **Number of participants analysed**: n = 20
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not described • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: classification system used in the Bergstrom Skin Assessment Tool that is equivalent to NPIAP/EPUAP system • **Definition (including ulcer stage)**: number of subjects with new pressure ulcers of stage 1 (least severe) to stage 4 (most severe) used in the Bergstrom Skin Assessment Tool • **Dropouts**: no missing • **Notes (e.g. other results reported)**: 12 of 20 (60%) in the Iris 3000 (4 Stage I and 8 Stage II) and 5 of 20 (25%) in MAXIFLOAT (2 Stage I and 3 Stage II)

	Time to pressure ulcer incidence • **Outcome type**: time-to-event • **Reporting**: partially reported • **Notes**: average number of days to pressure ulcer development 6.5 days on Iris 3000 and 9.2 days on MAXIFLOAT (not significantly different between groups, t[15] = 1.0095, P = 0.3288) *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported **Outcomes that are not considered in this review but reported in trials**: • Cost analysis
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Subjects meeting the admission criteria were randomly assigned by lot by the investigator who obtained the consent to use either the Iris 3000 or the MAXIFLOAT ... subjects were randomly assigned by research interviewer by drawing assignment out of a hat" Comment: low risk of bias because of the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes*** Comment: no attrition identified.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Whitney 1984

Study characteristics	
Methods	**Study objective**: to provide data that will assist nurses in determining which mattress is the best choice for pressure sore prevention, and under which circumstances **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: the average length of study 8.9 days in alternating pressure mattress; 7.6 in foam mattress **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: medical-surgical unit
Participants	**Baseline characteristics** **Inclusion criteria**: patients on 3 medical-surgical units who were in bed for 20 out of 24 hours daily **Exclusion criteria**: not described **Sex (M:F)**: not described **Age (years)**: mean 63.2 (range 19 to 91) **Baseline skin status**: people with ulcers included (2 had serious decubiti on admission, 1 in each of the groups) **Group difference**: not reported **Total number of participants**: n = 51 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Alternating pressure mattress • **Description of interventions**: an alternating pressure mattress consisting of 134 3-inch diameter air cells with a 2.5-inch lift, and micro air vents for air circulation. Adjacent air cells inflated and deflated alternately every 3 minutes. • **NPIAP S3I classification:** powered, alternating pressure (active) air surface • **Co-interventions**: routine nursing care received including turning every 2 hours • **Number of participants randomised**: n = 25 • **Number of participants analysed**: n = 25 Foam mattress • **Description of interventions**: a 4-inch polyurethane convoluted foam pad • **NPIAP S3I classification**: non-powered, reactive foam surface; polyurethane convoluted foam • **Co-interventions**: routine nursing care received including turning every 2 hours • **Number of participants randomised**: n = 26 • **Number of participants analysed**: n = 26
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary

- **Time points**: not described
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: not described
- **Definition (including ulcer stage)**: changes in skin condition; the definition of pressure ulcers not given
- **Dropouts**: not described
- **Notes (e.g. other results reported)**: 20% of 25 with worse skin condition, 20% with better condition, and 60% with the same condition in alternating pressure mattress; 23.1% with worse skin condition, 19.2% with better condition, and 57.7% with the same condition in foam mattress

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events of using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "26 were selected at random and placed in the foam mattress group, 25 in the AP mattress group" Comment: unclear risk of bias because it is unclear how random sequence was generated.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "... the investigators, who assessed the patient and placed him/her in one of the two mattress groups" Comment: high risk of bias because it is likely the investigators, i.e. key study personnel who operated the study, were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "In most cases patients were assessed by two investigators as a team, and occasionally by only one of the investigators" Quote: "The investigators who rated patient risk and evaluated skin condition knew the mattress assignment of each patient, making investigator bias possible" Comment: high risk of bias because non-blinding of outcome assessment is clearly stated.

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: no information provided.
Selective reporting (reporting bias)	Unclear risk	Comment: no information provided.
Other bias	Unclear risk	Comment: no information provided.

Whittingham 1999

Study characteristics	
Methods	**Study objective**: not given **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 12 months **Number of arms**: 6 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: elderly assessment unit
Participants	**Baseline characteristics** **Inclusion criteria**: at high risk of pressure sores (Waterlow) and dependent (Barthel); all patients admitted onto research mattresses were included, unless their skin had grade 3 (Stirling) or above pressure damage, or their skin condition deteriorated to grade 2/3 damage **Exclusion criteria**: not given **Sex (M:F)**: not given **Age (years)**: not given **Baseline skin status**: at high risk **Group difference**: not given **Total number of participants**: n = 309 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Improtec (Spenco International) • **Description of interventions**: Improtec (Spenco International) • **NPIAP S3I classification**: non-powered, reactive foam surface; insufficient information for specifying foam quality • **Co-interventions**: not described • **Number of participants randomised**: not given • **Number of participants analysed**: not given Pentaflex (Huntleigh Healthcare) • **Description of interventions**: Pentaflex (Huntleigh Healthcare) • **NPIAP S3I classification**: non-powered, reactive foam surface; insufficient information for specifying foam quality • **Co-interventions**: not described • **Number of participants randomised**: not given • **Number of participants analysed**: not given Serendipity (Talley)

	• **Description of interventions**: Serendipity (Talley) • **NPIAP S3I classification**: non-powered, reactive foam surface; insufficient information for specifying foam quality • **Co-interventions**: not described • **Number of participants randomised**: not given • **Number of participants analysed**: not given Softform • **Description of interventions**: Softform (Medical Support System) • **NPIAP S3I classification**: non-powered, reactive foam surface; high specification foam according to Gray 1994 • **Co-interventions**: not described • **Number of participants randomised**: not given • **Number of participants analysed**: not given Transwave • **Description of interventions**: Transwave (Karomed) • **NPIAP S3I classification**: non-powered, reactive foam surface • **Co-interventions**: not described • **Number of participants randomised**: not given • **Number of participants analysed**: not given Vapourlux • **Description of interventions**: Vapourlux (Parkhouse) • **NPIAP S3I classification**: non-powered, reactive foam surface; insufficient information for specifying foam quality • **Co-interventions**: not described • **Number of participants randomised**: not given • **Number of participants analysed**: not given
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: unclear • **Time points**: 12 months • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not given • **Definition (including ulcer stage)**: pressure sore incidence • **Dropouts**: not described • **Notes (e.g. other results reported)**: overall pressure sore incidence 16.5% (range 7 to 16.7% according to mattress), and the majority were grade 1 to 2 (Stirling) *Time to pressure ulcer incidence* • Not reported *Support-surface-associated patient comfort* • **Outcome type**: unclear • **Time points**: 12 months • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not given

	• **Definition**: patient comfort ratings • **Dropouts**: not given • **Notes:** comfort ratings were similarly good for all 6 mattresses initially. However, this altered by the end of the 12 months. *All reported adverse events using allocated support surfaces* • Not reported *Health-related quality of life (HRQOL)* • Not reported *Cost-effectiveness* • Not reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: unclear risk of bias because the sequence generation process was not described.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Quote: "Data were collected by a single researcher" Comment: unclear risk of bias because it is unclear if outcome assessment was blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: no information provided.
Selective reporting (reporting bias)	Unclear risk	Comment: no information provided.
Other bias	Unclear risk	Comment: no information provided.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
ACTRN12618000319279	Treatment study
Andersen 1982	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Andrews 1988	Ineligible study design - not a RCT
Anonymous 2006	Ineligible study design - review article
Aronovitch 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Ballard 1997	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)

Study	Reason for exclusion
Beeckman 2019	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Bell 1993	Ineligible study design - not a RCT
Bennett 1998	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Bliss 1966	Ineligible study design - not a RCT
Bliss 1967	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Bliss 1993	Ineligible study design - review article
Bliss 1995b	Ineligible study design - review article
Bliss 2003	Reproduction of previous work
Bliss 2004	Commentary on a trial
Branom 1999	Treatment study
Branom 2001	Treatment study
Brown 2001	Summary of the Cochrane Review McInnes 2015
Cadue 2008	This RCT was to compare heel-suspending device with the package of interventions
Caley 1994	Treatment study
Cassino 2013a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Cassino 2013b	Incorrect randomisation method (alternation to allocate patients into groups)
Cavicchioli 2007	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Chaloner 2000a	Incorrect randomisation method (quasi-randomisation)
ChiCTR1800017466	Ineligible interventions
Chou 2013	Review articles
Cobb 1997	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Conine 1990	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Cooper 1998	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Cummins 2019	Ineligible study design - quality improvement project without RCT design
Daechsel 1985	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Day 1993	Treatment study
Defloor 2005	Ineligible interventions - different combinations of turning and support surfaces under evaluations
Demarre 2012	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
De Oliveira 2017	Review article
Devine 1995	Treatment study
Economides 1995	This RCT was to observe the breakdown of flaps after operations rather than the incidence of new ulcers
Evans 2000	Treatment study
Ewing 1964	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Exton-Smith 1982	This trial used alternation to allocate patients into groups. Proper randomisation not completed.
Ferrell 1993	Treatment study
Ferrell 1995	Treatment study
Finnegan 2008	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Fleischer 1997	Ineligible study design

Study	Reason for exclusion
García Fernández 2004	Commentary on a RCT
Gazzerro 2008	Ineligible outcome (wound healing of flap surgery)
Gebhardt 1994a	Incorrect randomisation method (randomisation based on participants' hospital numbers)
Gebhardt 1994b	Incorrect randomisation method (randomisation based on participants' hospital numbers)
Gebhardt 1996	Incorrect randomisation method
Geelkerken 1994	Commentary
Goldstone 1982	Incorrect randomisation method
Gray 2008	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Greer 1988	Treatment study
Grindley 1996	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Groen 1999	Treatment study
Gunningberg 2001	Ineligible study design (cross sectional design)
Haalboom 1994	Commentary
Hale 1990	Ineligible study design (cost analysis without RCT data)
Hampton 1997	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Hampton 1998	Ineligible study design (not a RCT)
Hampton 1999	Ineligible study design (not a RCT)
Hawkins 1997	Ineligible study design (not a RCT)
Holzgreve 1993	Ineligible study design (not a RCT)
Hommel 2008	Ineligible study design (not a RCT)
Hoskins 2007a	Summary of findings of Nixon 2006
Hoskins 2007b	Summary of findings of Nixon 2006
Huang 2013	Review article
Huang 2018	Ineligible interventions (head pad rather than beds or mattresses)
Hungerford 1998	Commentary on a RCT
Iglesias 2006	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Inman 1993a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
IRCT2015110619919N3	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
IRCT2016091129781N1	Ineligible interventions (cushions rather than beds or mattresses)
Ismail 2001	Support surfaces used were not clearly specified. Unable to discover if the interventions were eligible for this review.
Jiang 2014	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Jolley 2004	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
JPRN-UMIN000029680	Treatment study
Keogh 2001	Ineligible interventions (profiling bed rather than beds or mattresses)
Klein 1989	Review article
Lazzara 1991	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Lee 1974	Ineligible study design (not a RCT)
Maklebust 1988	Ineligible interventions (cushions rather than beds or mattresses)
Malbrain 2010	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Marutani 2019	Incorrect randomisation method
Mastrangelo 2010a	Treatment study

Study	Reason for exclusion
McGinnis 2011	Review article
McGowan 2000	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
McInnes 2015	Review article
McInnes 2018	Review article
Mendoza 2019	Ineligible participants and outcome (flap closure)
Mistiaen 2010a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Mistiaen 2010b	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Nakahara 2012	Ineligible study design (not a RCT)
NCT01402765	Ineligible outcome (interface pressure)
NCT02565797	Ineligible study design (case control design)
NCT02634892	RCT with the comparison of reactive air surfaces versus standard hospital surfaces withdrawn due to funding issue
NCT02735135	Withdrew trial record with 'methodological difficulties' as the reason
NCT03048357	Ineligible interventions (rotation therapy versus turning)
NCT03211910	Ineligible interventions (not beds or mattresses)
NCT03351049	Ineligible interventions (reactive air surfaces versus reactive surfaces)
Nixon 1998	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Nixon 2006	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Ooka 1995	Ineligible study design (not a RCT)
Osterbrink 2005	Treatment study
Phillips 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Price 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Pring 1998	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Rae 2018	Review article
Rafter 2011	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Reddy 2006	Review article
Reddy 2008	Review article
Ricci 2013a	Treatment study
Ricci 2013b	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Rithalia 1995	Ineligible participants (healthy people)
Russell 1999	Treatment study
Russell 2000a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Russell 2000b	Treatment study
Russell 2000c	Treatment study
Russell 2003b	Treatment study
Sanada 2003	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Santy 1995	Review article
Scheffel 2011	Summary of a review
Scott 2000	Ineligible interventions
Scott-Williams 2006	Ineligible study design (not a RCT)
Serraes 2018	Review article
Shakibamehr 2019	Ineligible interventions (cushions rather than beds or mattresses)

Study	Reason for exclusion
Sharp 2007	Ineligible study design
Shi 2018a	Review article
Sideranko 1992	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Smith 2013	Review article
Stannard 1993	Commentary on a RCT
Sterzi 2003	Ineligible study design (not a RCT)
Strauss 1991	Treatment study
Takala 1994	Ineligible study design (not a RCT)
Taylor 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Tewes 1993	Review article
Theaker 2005	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Vanderwee 2005	Ineligible intervention (imbalanced use of co-interventions between study arms)
Van Rijswijk 1994	Commentary
Vermette 2012	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Wallace 2009	Review article
Yao 2018	Review article

Characteristics of studies awaiting classification [ordered by study ID]

Chaloner 2000b

Methods	Not available
Participants	Not available
Interventions	Two types of alternating pressure air surfaces
Outcomes	Not available
Notes	Unable to obtain full-text

Gardner 2008

Methods	Randomised controlled trial (2 arm)
Participants	**Inclusion criteria**: patients at risk of pressure injury (Waterlow score > 9) **Exclusion criteria**: under 16 years, unable to tolerate extended time lying supine and with sacral pressure injury of Stage 2 or above **Number of participants**: 66 **Age**: on average 68 (12.7) years **Gender** (M:F): 34:25 **Baseline skin status**: at risk of ulcer (Waterlow score > 9), without existing severe ulcers
Interventions	Airflotation and Ruby mattress • **Description of interventions**: alternating pressure air mattress • **NPIAP S3I classification:** powered, alternating pressure, active, air surface ComfortPlus mattress

	• **Description of interventions**: unspecified, probably foam surfaces • **NPIAP S3I classification**: non-powered, reactive, foam surfaces
Outcomes	**Outcomes of the interest of this review** • Unspecified **Outcomes unrelated to this review** • Interface pressure
Notes	

Henn 2004

Methods	Not available
Participants	Not available
Interventions	Alternating pressure air surfaces and a type of surface that cannot be defined
Outcomes	Not available
Notes	Unable to obtain full-text

Knight 1999

Methods	Not available
Participants	Not available
Interventions	Pressure relieving surfaces that cannot be defined
Outcomes	Not available
Notes	Unable to obtain full-text

Mastrangelo 2010b

Methods	Not available
Participants	Not available
Interventions	'Anti-decubitis lesion mattress cover' that cannot be defined
Outcomes	Not available
Notes	Unable to obtain full-text

Melland 1998

Methods	Not available
Participants	Not available
Interventions	'Freedom bed' that cannot be defined
Outcomes	Not available
Notes	Unable to obtain full-text

Appendices

Appendix 1. Full details of classifications of support surfaces

Overarching class of support surface (as used in this review)	Corresponding subclasses of support surfaces used in Shi 2018a	Descriptions of support surfaces	Selected examples (with example brands where possible)
Reactive air surfaces	Powered/non-powered reactive air surfaces	A group of support surfaces constructed of air cells, which redistribute body weight over a maximum surface area (i.e. has reactive pressure redistribution mode), with or without the requirement for electrical power	Static air mattress overlay, dry flotation mattress (e.g. Roho, Sofflex), static air mattress (e.g. EHOB), and static mode of Duo 2® mattress
	Powered/non-powered reactive low-air-loss air surfaces	A group of support surfaces made of air cells, which have reactive pressure redistribution modes and a low-air-loss function, with or without the requirement for electrical power	Low-air-loss Hydrotherapy
	Powered reactive air-fluidised surfaces	A group of support surfaces made of air cells, which have reactive pressure redistribution modes and an air-fluidised function, with the requirement for electrical power	Air-fluidised bed (e.g. Clinitron)
Foam surfaces	Non-powered reactive foam surfaces	A group of support surfaces made of foam materials, which have a reactive pressure redistribution function, without the requirement for electrical power	Convoluted foam overlay (or pad), elastic foam overlay (e.g. Aiartex, microfluid static overlay), polyether foam pad, foam mattress replacement (e.g. MAXIFLOAT), solid foam overlay, viscoelastic foam mattress/overlay (e.g. Tempur, CONFOR-Med, Akton, Thermo)
Alternative reactive support surfaces (non-foam or air-filled): reactive fibre surfaces	Non-powered reactive fibre surfaces	A group of support surfaces made of fibre materials, which have a reactive pressure redistribution function, without the requirement for electrical power	Silicore (e.g. Spenco) overlay/pad
Alternative reactive support surfaces (non-foam or air-filled): reactive gel surfaces	Non-powered reactive gel surfaces	A group of support surfaces made of gel materials, which have a reactive pressure redistribution function, without the requirement for electrical power	Gel mattress, gel pad used in operating theatre
Alternative reactive support surfaces (non-foam or air-filled): reactive sheepskin surfaces	Non-powered reactive sheepskin surfaces	A group of support surfaces made of sheepskin, which have a reactive pressure redistribution function, without the requirement for electrical power	Australian Medical Sheepskins overlay
Alternative reactive support surfaces (non-foam or air-filled): reactive water surfaces	Non-powered reactive water surfaces	A group of support surfaces based on water, which has the capability of a reactive pressure redistribution function, without the requirement for electrical power	Water mattress

Alternating pressure (active) air surfaces	Powered active air surfaces	A group of support surfaces made of air cells, which mechanically alternate the pressure beneath the body to reduce the duration of the applied pressure (mainly via inflating and deflating to alternately change the contact area between support surfaces and the body; i.e. alternating pressure, or active, mode), with the requirement for electrical power	Alternating pressure-relieving air mattress (e.g. Nimbus II, Cairwave, Airwave, MicroPulse), large-celled ripple
	Powered active low-air-loss air surfaces	A group of support surfaces made of air cells, which have the capability of alternating pressure redistribution as well as low air loss for drying local skin, with the requirement for electrical power	Alternating pressure low-air-loss air mattress
	Powered hybrid system air surfaces	A group of support surfaces made of air cells, which offer both reactive and active pressure redistribution modes, with the requirement for electrical power	Foam mattress with dynamic and static modes (e.g. Softform Premier Active)
	Powered hybrid system low-air-loss air surfaces	A group of support surfaces made of air cells, which offer both reactive and active pressure redistribution modes as well as a low air loss function, with the requirement for electrical power	Stand-alone bed unit with alternating pressure, static modes and low air-loss (e.g. TheraPulse)
Standard hospital surfaces	Standard hospital surfaces	A group of support surfaces made of any materials, used as-usual in a hospital and without reactive or active pressure redistribution capabilities, nor any other functions (e.g. low air loss, or air-fluidised)	Standard hospital (foam) mattress, National Health Service Contract hospital mattress, standard operating theatre surface configuration, standard bed unit and usual care

Appendix 2. Search strategies

Cochrane Wounds Specialised Register

1 MESH DESCRIPTOR beds EXPLODE ALL AND INREGISTER

2 mattress* AND INREGISTER

3 (foam or transfoam) AND INREGISTER

4 overlay* AND INREGISTER

5 (pad or pads) AND INREGISTER

6 gel AND INREGISTER

7 (pressure NEXT relie*) AND INREGISTER

8 (pressure NEXT reduc*) AND INREGISTER

9 (pressure NEXT alleviat*) AND INREGISTER

10 ("low pressure" near2 device*) AND INREGISTER

11 ("low pressure" near2 support) AND INREGISTER

12 (constant near2 pressure) AND INREGISTER

13 "static air" AND INREGISTER

14 (alternat* next pressure) AND INREGISTER

15 (air next suspension*) AND INREGISTER

16 (air next bag*) AND INREGISTER

17 (water next suspension*) AND INREGISTER

18 sheepskin AND INREGISTER

19 (turn* or tilt*) next (bed* or frame*) AND INREGISTER

20 kinetic next (therapy or table*) AND INREGISTER

21 (net next bed*) AND INREGISTER

22 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 AND INREGISTER

23 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND INREGISTER

24 (pressure next (ulcer* or sore* or injur*)) AND INREGISTER

25 (decubitus next (ulcer* or sore*)) AND INREGISTER

26 ((bed next sore*) or bedsore*) AND INREGISTER

27 #23 OR #24 OR #25 OR #26 AND INREGISTER

28 #22 AND #27 AND INREGISTER

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 MeSH descriptor: [Beds] explode all trees

#2 mattress*:ti,ab,kw

#3 (foam or transfoam):ti,ab,kw

#4 overlay*:ti,ab,kw

#5 "pad" or "pads":ti,ab,kw

#6 "gel":ti,ab,kw

#7 (pressure next relie*):ti,ab,kw

#8 (pressure next reduc*):ti,ab,kw

#9 (pressure next alleviat*):ti,ab,kw

#10 ("low pressure" near/2 device*):ti,ab,kw

#11 ("low pressure" near/2 support):ti,ab,kw

#12 (constant near/2 pressure):ti,ab,kw

#13 "static air":ti,ab,kw

#14 (alternat* next pressure):ti,ab,kw

#15 (air next suspension*):ti,ab,kw

#16 (air next bag*):ti,ab,kw

#17 (water next suspension*):ti,ab,kw

#18 sheepskin:ti,ab,kw

#19 (turn* or tilt*) next (bed* or frame*):ti,ab,kw

#20 kinetic next (therapy or table*):ti,ab,kw

#21 (net next bed*):ti,ab,kw

#22 {or #1-#21}

#23 MeSH descriptor: [Pressure Ulcer] explode all trees

#24 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw

#25 (decubitus next (ulcer* or sore*)):ti,ab,kw

#26 ((bed next sore*) or bedsore*):ti,ab,kw

#27 {or #23-#26}

#28 (#22 and #27) in Trials

Ovid MEDLINE

1 exp Beds/

2 mattress*.mp.

3 (foam or transfoam).mp.

4 overlay*.mp.

5 (pad or pads).ti,ab.

6 gel.ti,ab.

7 pressure relie*.mp.

8 pressure reduc*.mp.

9 pressure alleviat*.mp.

10 (low pressure adj2 device*).mp.

11 (low pressure adj2 support).mp.

12 (constant adj2 pressure).mp.

13 static air.mp.

14 (alternat* adj pressure).mp.

15 air suspension*.mp.

16 air bag*.mp.

17 water suspension*.mp.

18 sheepskin.mp.

19 ((turn* or tilt*) adj (bed* or frame*)).mp.

20 (kinetic adj (therapy or table*)).mp.

21 net bed*.mp.

22 or/1-21

23 exp Pressure Ulcer/

24 (pressure adj (ulcer* or sore*)).mp.

25 (decubitus adj (ulcer* or sore*)).mp.

26 (bed adj (ulcer* or sore*)).mp.

27 or/23-26

28 and/22,27

29 randomized controlled trial.pt.

30 controlled clinical trial.pt.

31 randomi?ed.ab.

32 placebo.ab.

33 clinical trials as topic.sh.

34 randomly.ab.

35 trial.ti.

36 or/29-35

37 exp animals/ not humans.sh.

38 36 not 37

39 28 and 38

Ovid Embase

1 exp Bed/

2 mattress*.mp.

3 (foam or transfoam).mp.

4 overlay*.mp.

5 (pad or pads).ti,ab.

6 gel.ti,ab.

7 pressure relie*.mp.

8 pressure reduc*.mp.

9 pressure alleviat*.mp.

10 (low pressure adj2 device*).mp.

11 (low pressure adj2 support).mp.

12 (constant adj2 pressure).mp.

13 static air.mp.

14 (alternat* adj pressure).mp.

15 air suspension*.mp.

16 air bag*.mp.

17 water suspension*.mp.

18 sheepskin.mp.

19 ((turn* or tilt*) adj (bed* or frame*)).mp.

20 (kinetic adj (therapy or table*)).mp.

21 net bed*.mp.

22 or/1-21

23 exp Decubitus/

24 (pressure adj (ulcer* or sore*)).mp.

25 (decubitus adj (ulcer* or sore*)).mp.

26 (bed adj (ulcer* or sore*)).mp.

27 or/23-26

28 and/22,27

29 Randomized controlled trials/

30 Controlled clinical study/

31 Single-Blind Method/

32 Double-Blind Method/

33 Crossover Procedure/

34 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab.

35 (doubl* adj blind*).ti,ab.

36 (singl* adj blind*).ti,ab.

37 or/29-36

38 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/

39 human/ or human cell/

40 and/38-39

41 38 not 40

42 37 not 41

43 28 and 42

EBSCO CINAHL Plus

S50 S26 AND S49

S49 S48 NOT S47

S48 S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41

S47 S45 NOT S46

S46 MH (human)

S45 S42 OR S43 OR S44

S44 TI (animal model*)

S43 MH (animal studies)

S42 MH animals+

S41 AB (cluster W3 RCT)

S40 MH (crossover design) OR MH (comparative studies)

S39 AB (control W5 group)

S38 PT (randomized controlled trial)

S37 MH (placebos)

S36 MH (sample size) AND AB (assigned OR allocated OR control)

S35 TI (trial)

S34 AB (random*)

S33 TI (randomised OR randomized)

S32 MH cluster sample

S31 MH pretest-posttest design

S30 MH random assignment

S29 MH single-blind studies

S28 MH double-blind studies

S27 MH randomized controlled trials

S26 S20 AND S25

S25 S21 OR S22 OR S23 OR S24

S24 TI decubitus or AB decubitus

S23 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)

S22 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)

S21 (MH "Pressure Ulcer")

S20 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19

S19 TI net bed* or AB net bed*

S18 TI (kinetic therapy or kinetic table*) or AB (kinetic therapy or kinetic table*)

S17 TI (turn* bed* or tilt* bed*) or AB (turn* frame* or tilt* frame*)

S16 TI sheepskin OR AB sheepskin

S15 TI water suspension or AB water suspension

S14 TI air bag* or AB air bag*

S13 TI air suspension or AB air suspension

S12 TI alternat* pressure or AB alternat* pressure

S11 TI static air or AB static air

S10 TI constant N2 pressure or AB constant N2 pressure

S9 TI low pressure N2 support or AB low pressure N2 support

S8 TI low pressure N2 device* or AB low pressure N2 device*

S7 TI pressure alleviat* or AB pressure alleviat*

S6 TI pressure reduc* or AB pressure reduc*

S5 TI pressure relie* or AB pressure relie*

S4 TI (overlay* or pad or pads or gel) or AB (overlay* or pad or pads or gel)

S3 TI (foam or transfoam) or AB (foam or transfoam)

S2 TI mattress* or AB mattress*

S1 (MH "Beds and Mattresses+")

US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov)

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcer

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Injury

bed OR mattress OR sheepskin OR gel OR pad OR foam OR pressure OR support OR air | Pressure Ulcers buttock

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Ulcer, Pressure

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcer Stage 1

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcers Stage II

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcers Stage III

World Health Organization International Clinical Trials Registry Platform

pressure ulcer [title] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure ulcer [condition] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure injury [title] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure injury [condition] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

Appendix 3. Risk of bias

1 'Risk of bias' assessment in individually randomised controlled trials

1. Was the allocation sequence randomly generated?

Low risk of bias

The study authors describe a random component in the sequence generation process, such as referring to a random number table, using a computer random number generator, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots.

High risk of bias

The study authors describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example, sequence generated by odd or even date of birth, sequence generated by some rule based on date (or day) of admission, sequence generated by some rule based on hospital or clinic record number.

Unclear

Insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

2. Was the treatment allocation adequately concealed?

Low risk of bias

Participants and study authors enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes.

High risk of bias

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, e.g. allocation was based on using an open random allocation schedule (e.g. a list of random numbers); or assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered), alternation or rotation, date of birth, case record number, any other explicitly unconcealed procedure.

Unclear

Insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

3. Blinding: was knowledge of the allocated interventions by participants and personnel adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others is likely to introduce bias.

Unclear

Any one of the following.

- Insufficient information to permit a judgement of low or high risk of bias.
- The study did not address this outcome.

4. Blinding: was knowledge of the allocated interventions by outcome assessors adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding.
- Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome measurement is likely to be influenced by lack of blinding.
- Blinding of outcome assessment attempted, but likely that the blinding could have been broken.

Unclear

Any one of the following.

- Insufficient information to permit a judgement of low or high risk of bias.
- The study did not address this outcome.

5. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.

- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk is not sufficient to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, the plausible effect size (difference in means or standardised difference in means) among missing outcomes is not sufficient to have a clinically relevant impact on observed effect size.
- Missing data have been imputed using appropriate methods.

High risk of bias

Any one of the following.

- Reason for missing outcome data is likely to be related to the true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk is sufficient to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, the plausible effect size (difference in means or standardised difference in means) among missing outcomes is sufficient to induce clinically relevant bias in the observed effect size.
- 'As-treated' analysis done, with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Any one of the following.

- Insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated; no reasons for missing data provided).
- The study did not address this outcome.

6. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Any of the following.

- The study protocol is available and all of the study's prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).

High risk of bias

Any one of the following.

- Not all of the study's prespecified primary outcomes have been reported.
- One or more primary outcomes are reported using measurements, analysis

methods or subsets of the data (e.g. subscales) that were not prespecified.

- One or more reported primary outcomes were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

Insufficient information to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

7. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

2 'Risk of bias' assessment in cluster-randomised controlled trials (cluster-RCTs)

1. Recruitment bias

Recruitment bias (or identification bias) is the bias that occurs in cluster-RCTs if the personnel recruiting participants know individuals' allocation, even when the allocation of clusters has been concealed appropriately. The knowledge of the allocation of clusters may lead to bias because the individuals' recruitment in cluster trials is often behind the clusters' allocation to different interventions; and the knowledge of allocation can determine whether individuals are recruited selectively.

This bias can be judged through considering the following questions.

- Were all the individual participants identified/recruited before randomisation of clusters?
- Is it likely that selection of participants was affected by knowledge of the intervention?
- Were there baseline imbalances that suggest differential identification or

recruitment of individual participants between arms?

2. Baseline imbalance

Baseline imbalance between intervention groups can occur due to chance, problems with randomisation, or identification/recruitment bias. The issue of recruitment bias has been considered above.

In terms of study design, the risk of chance baseline imbalance can be reduced by the use of stratified or pair-matched randomisation. Minimisation — an equivalent technique to randomisation — can be used to achieve better balance in cluster characteristics between intervention groups if there is a small number of clusters.

Concern about the influence of baseline imbalance can be reduced if studies report the baseline comparability of clusters, or statistical adjustment for baseline characteristics.

3. Loss of clusters

Similar to missing outcome data in individually randomised trials, bias can occur if clusters are completely lost from a cluster-RCT, and are omitted from the analysis.

The amount of missing data, the reasons for missingness and the way of analysing data given the missingness should be considered in assessing the possibility of bias.

4. Incorrect analysis

Data analyses, which do not take the clustering into account, in cluster-RCTs will be incorrect. Such analyses lead to a 'unit of analysis error' and over-precise results (overly small standard error) and overly small P values. Though these analyses will not result in biased estimates of effect, they (if not correctly adjusted) will lead to too much weight allocated to cluster trials in a meta-analysis.

Note that the issue of analysis may not lead to concern any more and will not be considered substantial if approximate methods are used by review authors to address clustering in data analysis.

5. Comparability with individually randomised trials

In the case that a meta-analysis includes, for example, both cluster-randomised and individually randomised trials, potential differences in the intervention effects between different trial designs should be considered. This is because the 'contamination' of intervention effects may occur in cluster-RCTs, which would lead to underestimates of effect. The contamination could be known as a 'herd effect': that is, within clusters, individuals' compliance with using an intervention may be enhanced, which in return affects the estimation of effect.

Appendix 4. Specific support surfaces in the included studies classed and grouped by comparisons

Study ID	Foam surfaces	Comparators
Foam surfaces versus another type of foam surfaces		

Bueno de Camargo 2018	Viscoelastic mattress • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high specification (viscoelastic) foam (density of 40 and 60)	Standard mattress with pyramidal overlay • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; foam with a density of 33
Collier 1996	Multiple types of foam mattresses, each served as an arm in Collier 1996 • Omnifoam (HNE Healthcare) • Softform (Medical Support System) • Transfoam (Karomed) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification foam according to Gray 1994; Gray 2000; Santy 1994	Multiple arms, each served as an arm in Collier 1996; and the NHS standard foam mattress appeared to be the control in Collier 1996 • Clinifloat (SSI Medical Services Ltd) • STM5 (Servies to Medicine) • Therarest (KCI Medical Ltd) • Vapourlux (Parkhouse) • NHS standard contract 130 mm foam mattress (Reylon Ltd) • **NPIAP S3I classification**: non-powered, reactive, foam, surfaces; foam characteristics unspecified
Gray 1994	Softform mattress (Medical Support Systems Ltd) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification foam	Standard 130 mm foam mattress (Recticel Ltd.) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; foam characteristics unspecified
Gray 2000	Transfoam • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification foam	Transfoamwave • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification foam
Kemp 1993	Convoluted foam mattress overlay • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; 3-in. or 4-in., density 22.7 kg/m^3 foam	Solid foam mattress overlay • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; 4-in. density 21.3 kg/m^3 foam
Ozyurek 2015	Viscoelastic foam 1 • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; multi-layered, viscoelastic polyurethane, 8 cm of high-flexibility foam	Viscoelastic foam 2 • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; multi-layered, viscoelastic foam
Santy 1994	Multiple types of foam mattresses, each served as an arm in Santy 1994; Omnifoam not included in this review due to data unavailability and NHS Contract appeared to be the control in Santy 1994 • Omnifoam (Huntleigh Nesbit Evans Healthcare), with high density foam	Multiple types of foam mattresses, each served as an arm in Santy 1994 • Clinifloat (SSI Medical Sevices Ltd) • Therarest (KCI Therapeutic Services)

	• Transfoam (Karomed Ltd), 150 mm thick, foam density of 30-33 kg/m^3 and hardness 145-170 N • Vaperm (Huntleigh Nesbit Evans Healthcare), foam density from 35 kg/m^3 to 60 kg/m^3, with the inner core of high density ventitated foam • NHS Contract (150 mm) (Reylon Ltd), using high resilience polyether foam with a density of 39 - 42 kg/m^3 and hardness index of 170 N • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high specification foam	• **NPIAP S3I classification**: non-powered, reactive, foam surfaces; foam characteristics unspecified
Vyhlidal 1997	MAXIFLOAT • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high specification (high-resiliency, 29 lb IFD, polyurethane) foam	Iris 3000 • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; 4-in., density of 28.8 kg/m^3) foam
Whittingham 1999	Softform (Medical Support System) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification foam	Five types of foam mattresses, each served as an arm in Whittingham 1999: • Improtec (Spenco International) • Pentaflex (Huntleigh Healthcare) • Serendipity (Talley) • Transwave • Vapourlux • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; all lack of sufficient information for specifying foam characteristics
Foam surfaces versus alternating pressure (active) air surfaces		
Bliss 1995a	Three types of foam mattresses, each served as an arm in Bliss 1995a: • Groove contoured foam overlay • Modular Propad • Preventix foam mattress • **NPIAP S3I classification**: non-powered, reactive, foam, surfaces; foam characteristics unspecified	Large cell Ripple bed (with a 10-minute interval of alternating pressure) • **NPIAP S3I classification:** powered, alternating pressure, active, air cells, surfaces

Nixon 2019	High-specification foam mattress (high-density foam, and/or viscoelastic (memory) foam) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification foam	Alternating pressure air mattress (with a 7.5–30 minute cycle time) • **NPIAP S3I classification:** powered, alternating pressure, active, air cells, surfaces
Rosenthal 2003	A medium density polyurethane foam overlay • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; polyurethane foam	Low air loss suspension bed (TheraPulse bed) • **NPIAP S3I classification:** powered, alternating pressure, active, air cells, surfaces; low air loss
Sauvage 2017	Viscoelastic foam mattress (ALOVA mattress, high resilience foam with a density > 34kg/m^3 and an upper layer of viscoelastic foam of density > 75kg/m^3) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification foam	Alternating pressure air mattress (Axtair One, with a 6-minute cycle) • **NPIAP S3I classification:** powered, alternating pressure, active, air cells, surfaces
Stapleton 1986	Polyether foam pad, more details not specified • **NPIAP S3I classification**: non-powered, reactive, foam, surfaces	Large Cell Ripple (Talley) • **NPIAP S3I classification:** powered, alternating pressure, active, air cells, surfaces
Whitney 1984	A polyurethane convoluted foam pad, more details not specified • **NPIAP S3I classification**: non-powered, reactive, foam, surfaces	Alternating pressure mattress (with a 3-minute cycle) • **NPIAP S3I classification:** powered, alternating pressure, active, air cells, surfaces
Foam surfaces versus reactive air surfaces		
Allman 1987	Conventional therapy (a vinyl alternating air-mattress covered by a 19-mm thick foam pad) • **NPIAP S3I classification**: non-powered, reactive, foam, surfaces	Air-fluidized bed (Clinitron Therapy, Support Systems International, Inc.) • **NPIAP S3I classification**: non-powered, reactive, air surfaces; air-fluidised
Takala 1996	Standard hospital mattress (10 cm thick foam mattress, density 35 kg/m^3, Espe Inc) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high specification (density 35 kg/m^3) foam	Constant low pressure air mattress (Carital Optima, Carital Ltd) • **NPIAP S3I classification:** powered, reactive, air surfaces
Van Leen 2011	15 cm cold foam mattress • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; elastic polyurethane foam	Static air overlay • **NPIAP S3I classification**: non-powered, reactice, air surfaces

Van Leen 2013	Standard visco-elastic foam mattress • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; viscoelastic foam	Static air overlay • **NPIAP S3I classification**: non-powered, reactive, air surfaces
Foam surfaces versus reactive water surfaces		
Bliss 1995a	Three types of foam mattresses, each served as an arm in Bliss 1995a: • Groove (a contoured 10-cm thick foam overlay) • Propad (an 8.5-cm thick foam pad • Preventix (a 16-cm thick mat of 8-cm square foam modules of different densities) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; foam characteristics unspecified	Ardo Watersoft • **NPIAP S3I classification**: non-powered, reactive, water surfaces
Foam surfaces versus reactive fibre surfaces		
Bliss 1995a	Three types of foam mattresses, each served as an arm in Bliss 1995a: • Groove (a contoured 10-cm thick foam overlay) • Propad (an 8.5 cm thick foam pad • Preventix (a 16-cm thick mat of 8-cm square foam modules of different densities) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; foam characteristics unspecified	Two types of fibre-filled mattresses, each served as an arm in Bliss 1995a: • Spenco (cotton hollow-core fibre-filled) • Surgicgoods Hollowcore Mattress fibre-filled pad • **NPIAP S3I classification**: non-powered, reactive, fibre surfaces
Stapleton 1986	Polyether foam pad (2 feet x 2 feet x 3-inch thickness) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces	Spenco pad • **NPIAP S3I classification**: non-powered, reactive, fibre surfaces
Foam surfaces versus reactive foam and gel surfaces		
Hoshowsky 1994	Standard foam mattress (a standard vinyl covered 2-inch thick foam operating room table mattress) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces	A 2-inch thick foam and gel operating room table mattress • **NPIAP S3I classification**: non-powered, reactive, foam and gel surfaces
Foam surfaces versus reactive gel mattress		

Hoshowsky 1994	Standard foam mattress (a standard vinyl covered 2-inch thick foam operating room table mattress) • **NPIAP S3I classification**: non-powered, reactive, foam, surfaces	A viscoelastic dry polymer mattress overlay (VEO-Action®) on the top of the foam and gel mattress • **NPIAP S3I classification**: non-powered, reactive, gel surfaces
Hoshowsky 1994	Standard foam mattress (a standard vinyl covered 2-inch thick foam operating room table mattress) • **NPIAP S3I classification**: non-powered, reactive, foam, surfaces	VEO-Action® on the top of standard foam mattress • **NPIAP S3I classification**: non-powered, reactive, gel surfaces
Foam surfaces versus undefined reactive surfaces		
Van Leen 2018	Viscoelastic foam mattress (Formafoam) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; viscoelastic foam	Multilayer mattress system (thickness of 13 mm) (Bedcare; Sense Textile's-Hertogenbosch) on viscoelastic foam mattress • NPIAP **S3I classification** *:* reactive surfaces; undefined materials
Foam surfaces versus standard hospital surfaces		
Berthe 2007	Kliniplot® mattress • **NPIAP S3I classification**: non-powered, reactive, foam surfaces	Standard hospital surfaces, without more details
Feuchtinger 2006	Test operating room table (a 4-cm thermoactive visco-elastic foam pad combined with a warming mattress on the operating table) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; 4-cm viscoelastic foam operating table	Standard operating room table (a warming mattress on the operating table, no pressure-reducing device) • NPIAP **S3I classification**: standard hospital surfaces
Gunningberg 2000	Visco-elastic foam mattress (a 10cm thick visco-elastic foam mattress foam, Tempur-Pedic in A&E; and a 7cm visco-elastic foam overlay in the wards) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification (viscoelastic, density of 35 kg/m^3) foam	Standard hospital mattress (routine standard trolley 5 cm mattress; and standard 10cm Prodenso foam hospital mattress in the ward) • NPIAP **S3I classification**: standard hospital surfaces
Hofman 1994	Comfortex DeCube mattress • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification (high resilience) foam	Standard hospital mattress (Vredestein polypropylene SG 40 hospital mattress) • NPIAP **S3I classification**: standard hospital surfaces
Laurent 1998	Comparison (a): Tempur (CLP) postoperatively and standard mattress in ICU (details of standard mattress not specified)	Comparison (a): standard hospital mattresses used in both ICU and post-operation (details of standard mattress not specified)

	Comparison (b): Tempur (CLP) used postoperatively and Nimbus in ICU • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification foam	Comparison (b): standard mattress applied postoperatively and Nimbus used in ICU (details of standard mattress not specified) • NPIAP **S3I classification**: standard hospital surfaces
Park 2017	Viscoelastic foam overlay (VEFO) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; high-specification (viscoelastic polyurethane polyester, hardness 40%) foam	Standard hospital surfaces
Russell 2003a	CONFOR-Med mattress/cushion combination • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; (multi-layered, viscoelastic and polyurethane) foam	Standard mattress/cushion combination (King's Fund, Linknurse, Softfoam, or Transfoam, or a King's Fund mattress with a Spenco or Propad mattress overlay) • NPIAP **S3I classification**: standard hospital surfaces
Schultz 1999	New mattress overlay (made of foam with a 25% ILD of 30 pounds and a density of 1.3) • **NPIAP S3I classification**: non-powered, reactive, foam surfaces; (density 20.8 kg/m^3) foam	Usual perioperative care/ standard surgical care (including gel pads, foam egg crate mattresses, and foam donuts for the heels and elbows) • NPIAP **S3I classification**: standard hospital surfaces

Appendix 5. Results of studies with surfaces that could not be classified

Outcomes	Results
Comparison: Foam surfaces compared with surfaces that could not be classified	
Proportion of participants developing a new pressure ulcer (follow-up duration minimum 5 days, maximum 7 months)	• Eight studies (4066 participants) that compared foam surfaces with undefined 'standard hospital surfaces' reported inconsistent results: five (3485 participants) reported no difference in the proportion of participants developing a new pressure ulcer between these surfaces (Berthe 2007; Feuchtinger 2006; Gunningberg 2000; Laurent 1998; Russell 2003a); two (168 participants) suggested foam surfaces reduced the risk of having new pressure ulcers (Hofman 1994; Park 2017); one (413 participants) suggested foam surfaces increased the risk (Schultz 1999). • Van Leen 2018 (206 participants) compared foam surfaces with the Bedcare surface. The study reported that 5 of 103 (4.9%) people using foam surfaces developed a new pressure ulcer and 9 of 103 (8.7%) people using undefined reactive surfaces developed new ulcers. The RR is 0.56 (95% CI 0.19 to 1.60).
Time to pressure ulcer incidence (follow-up duration minimum 5 days, maximum 7 months)	Three studies (3072 participants) that compared foam surfaces with undefined 'standard hospital surfaces' reported this outcome measure: Berthe 2007 (1729 participants) suggested foam surfaces reduced the hazard of developing a new ulcer whilst Feuchtinger 2006 and Russell 2003a (1343 participants) suggested no difference between foam surfaces and 'standard hospital

	surfaces'.
Support-surface-associated patient comfort (follow-up duration minimum 11.5 days, maximum 14.0 days)	Two studies (1269 participants) that compared foam surfaces with undefined 'standard hospital surfaces' reported this outcome (Gunningberg 2000; Russell 2003a). The two studies reported different measures and outcome data: Gunningberg 2000 measured comfort using a five point scale (higher score = better comfort) and reported a mean rating of comfort of 4.2 for foam surfaces and 4.0 for standard hospital mattress. Russell 2003a measured this using a ten point scale (higher score = poorer comfort) but reported no significant differences in comfort between foam mattresses (mean 2.33 and SD 0.98) and standard hospital mattress (mean 2.46 and SD 1.0).
All reported adverse events (follow-up duration 12 weeks)	Van Leen 2018 (206 participants) compared foam surfaces with Bedcare surfaces. The study reported this outcome but stated that there was no reported adverse events in either study group. It is uncertain if there is a difference in the adverse effects between foam surfaces and the undefined reactive surfaces. Evidence was of very low certainty, downgraded twice for high risk of bias in a domain other than performance bias, and once for imprecision as the sample size was small and the number of events was relatively low.
Cost-effectiveness (follow-up duration 11.5 days)	Russell 2003a (1168 participants) compared foam surfaces with undefined 'standard hospital surfaces'. The study reported this outcome using two measures: cost per any pressure ulcer (including blanching erythema) prevented; and cost per non-blanching erythema (or worse) avoided. The results suggest that foam surfaces have a 88% probability of being cost effective compared with standard hospital surfaces in preventing any pressure ulcer (including blanching erythema); and have a 95% probability of being cost effective in preventing non-blanching erythema or worse.

Appendix 6. Sensitivity analyses

Sensitivity analysis	Studies	Participants	Statistical Method	Effect Estimate
Comparison: Foam surfaces compared with alternating pressure (active) air surfaces				
Outcome: Proportion of participants developing a new pressure ulcer				
• Sensitivity analysis using fixed-effect model	4	2247	Risk Ratio (M-H, Fixed, 95% CI)	1.41 [1.08, 1.83]
• Sensitivity analysis with time to pressure ulcer incidence as the primary outcome	2		Hazard Ratio (IV, Random, 95% CI)	2.46 [0.61, 9.88]
• Post-hoc sensitivity analysis using pressure ulcer incidence data from Nixon 2019 only	1	2029	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [0.96, 1.74]
Comparison: Foam surfaces compared with reactive air surfaces				
Outcome: Proportion of participants developing a new pressure ulcer				
• Sensitivity analysis using fixed effect model	4	229	Risk Ratio (M-H, Fixed, 95% CI)	2.47 [1.40, 4.38]

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Figures and tables

Additional tables

Table 1

All reported adverse events

Study ID	Results		Comment
Comparison: foam surfaces versus alternating pressure (active) air surfaces			
Nixon 2019	Related and unexpected serious adverse events: 0 Expected adverse events/ serious adverse events: 167/1013 The proportion of deaths: 84/1013, 8.3% Re-admission rates: 62/1013, 6.1% Fall rates: 159/1013, 15.7%	Related and unexpected serious adverse events: 0 Expected adverse events/ serious adverse events: 163/1017 The proportion of deaths: 82/1017, 8.1% Re-admission rates: 82/1017, 8.1% Fall rates: 152/1017, 14.9%	Similar between groups
Rosenthal 2003	See comment	See comment	One death; but the authors did not specify which group the death was in.
Sauvage 2017	• No serious adverse events (SAEs) reported • Twenty adverse events, including 1 hyperalgesia	• Serious adverse events: 2 deaths, a massive septic shock with acute pulmonary oedema and a decompensation of an insulin-dependent diabetes. • Twenty adverse events, including 2 discomforts.	Events other than discomfort and hyperalgesia did not involve the mattresses. It is unclear if adverse events were reported per individual participants.
Comparison: Foam surfaces versus reactive air surfaces			
Allman 1987	Death: 7 Pneumonia: 4 Urinary tract infections: 7 Hypotension: 7 Hypernatraemia: 5 Oliguria: 8 Sepsis: 6 Fever: 22 Heart failure: 6	Death: 8 Pneumonia: 2 Urinary tract infections: 10 Hypotension: 6 Hypernatraemia: 5 Oliguria: 5 Sepsis: 7 Fever: 16 Heart failure: 3	Some patients appeared to have multiple adverse events.

Table 2

Pressure ulcer incidence results reported in studies that compared different types of foam surfaces

Study ID	Results	Comment
Comparison: foam surfaces compared with other types of foam surfaces		

Bueno de Camargo 2018	Viscoelastic mattress (foam density of 40 and 60) • Proportion of participants developing a new pressure ulcer: 10/31 (32.3%) • Time to pressure ulcer incidence: median time to develop an ulcer 8.5 days (interquartile range (IQR) 5.0–14.0)	Standard mattress with pyramidal overlay (foam with a density of 33) • Proportion of participants developing a new pressure ulcer: 25/31 (80.6%) • Time to pressure ulcer incidence: median time to develop an ulcer 6.0 days (IQR 3.0–8.0)	• Proportion of participants developing a new pressure ulcer: RR 0.40 (95% CI 0.23 to 0.69) • Time to pressure ulcer incidence: Mann-Whitney test P value = 0.088; HR 0.33 (95% CI 0.17 to 0.64), estimated by the review authors using the methods described in Tierney 2007
Collier 1996	Multiple types of foam mattresses, each served as an arm in Collier 1996 • Omnifoam (HNE Healthcare) • Softform (Medical Support System) • Transfoam (Karomed) These could be defined as 'high specification foam surfaces' • Proportion of participants developing a new pressure ulcer: 0/33 (0%)	Multiple arms, each served as an arm in Collier 1996; and the NHS standard foam mattress appeared to be the control in Collier 1996 • Clinifloat (SSI Medical Services Ltd) • STM5 (Servies to Medicine) • Therarest (KCI Medical Ltd) • Vapourlux (Parkhouse) • NHS standard contract 130 mm foam mattress (Reylon Ltd) • Proportion of participants developing a new pressure ulcer: 0/57 (0%)	• Proportion of participants developing a new pressure ulcer: summary estimate not estimable
Gray 2000	Transfoamwave • Proportion of participants developing a new pressure ulcer: 2/50 (4.0%)	Transfoam • Proportion of participants developing a new pressure ulcer: 2/50 (4.0%)	• Proportion of participants developing a new pressure ulcer: RR 1.00 (95% CI 0.15 to 6.82)
Kemp 1993	Convoluted foam mattress overlay (foam surfaces 3-inch or 4-inch, density 22.7 kg/m^3) • Proportion of participants	Solid foam mattress overlay (foam surfaces 4-inch density 21.3 kg/m^3) • Proportion of participants developing a new	• Proportion of participants developing a new pressure ulcer: RR 1.52 (95% CI 0.86 to 2.67) • Time to pressure ulcer incidence: hazard ratio for convoluted foam vs solid foam of exp(0.906) = 2.47 and P = 0.018 (HR 2.47,

	developing a new pressure ulcer: 21/45 (46.7%) • Time to pressure ulcer incidence: see comments	pressure ulcer: 12/39 (30.8%) • Time to pressure ulcer incidence: see comments	95% CI 1.25 to 4.90) in a Cox regression model adjusted for mobility score (solid foam as reference). The risk of developing a pressure ulcer was greater for patients nursed on convoluted foam than for patients nursed on solid foam when the averaged mobility score was also taken into account.
Ozyurek 2015	Multi-layered, viscoelastic polyurethane, 8 cm of high-flexibility foam • Proportion of participants developing a new pressure ulcer: 22/178 (12.4%)	Multi-layered, viscoelastic foam • Proportion of participants developing a new pressure ulcer: 23/179 (12.8%)	• Proportion of participants developing a new pressure ulcer: RR 0.96 (95% CI 0.56 to 1.66)
Vyhlidal 1997	MAXIFLOAT (29 lb indentation force load deflection (IFD), polyurethane foam) • Proportion of participants developing a new pressure ulcer: 5/20 (25.0%)	Iris 3000 (4-inch, density of 28.8 kg/m^3) foam) • Proportion of participants developing a new pressure ulcer: 12/20 (60.0%)	• Proportion of participants developing a new pressure ulcer: RR 0.42 (95% CI 0.18 to 0.96)

Table 3

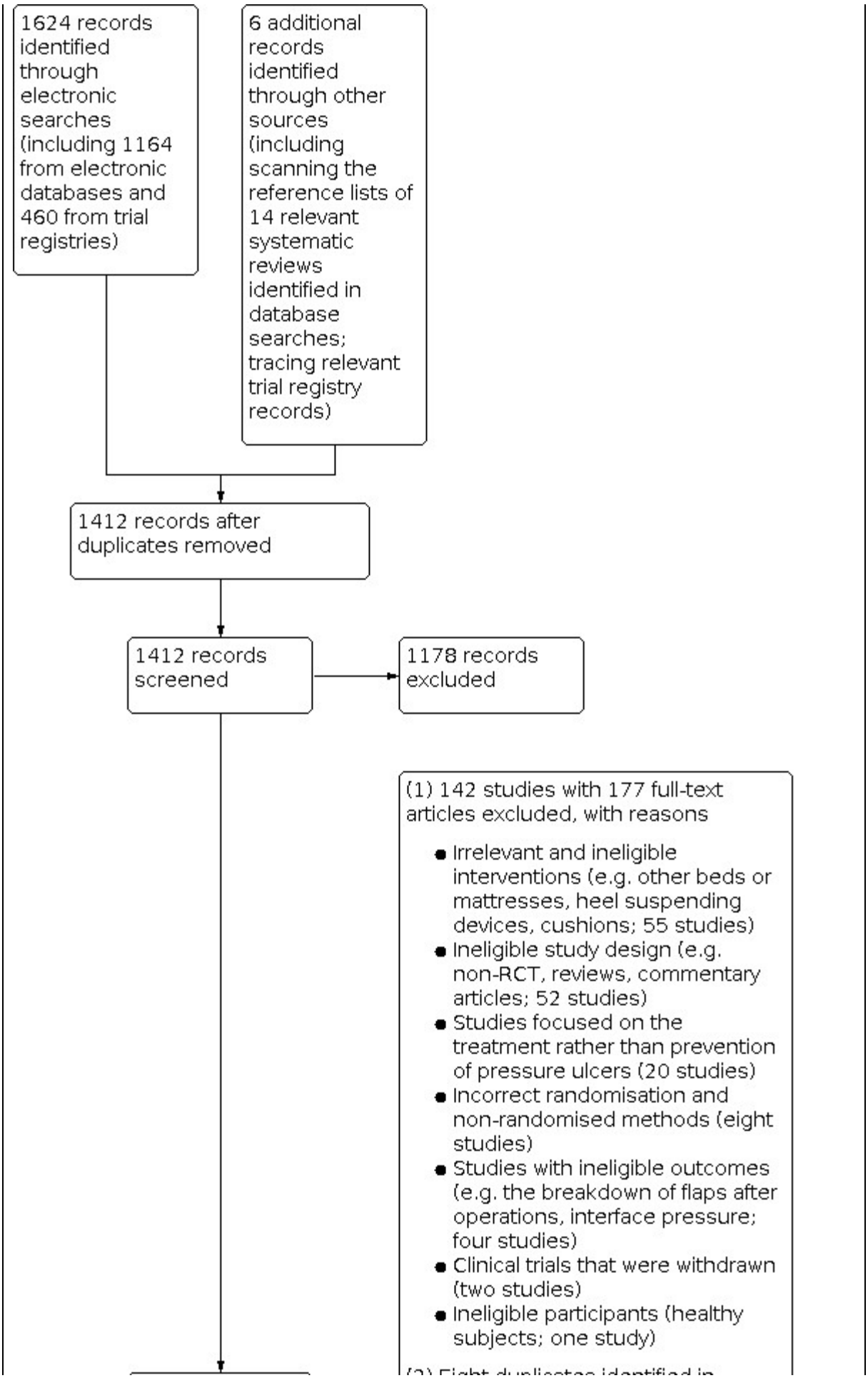
Support surface associated patient comfort results reported in studies that were not analysed

Study ID	Results		Comments
Comparison: foam surfaces vs another type of foam surfaces			
Collier 1996	Range of patient comfort results • Omnifoam (n = 11): 3 to 8 • Softform (n = 12): 8 to 11 • Transfoam (n = 10): 2 to 8	Range of patient comfort results • Clinifloat (n = 11): 5 to 7 • NHS Standard (n = 9): 0 to 0 • STM5 (n = 10): 9 to 9 • Therarest (n = 13): 8 to 8 • Vapourlux (n = 14): 10 to 10	Patient comfort assessed using a standardised question and visual rating scale (1 = poor, 10 = excellent)
Gray 1994	• Softform Very uncomfortable 0/90 Uncomfortable 0/90	• Standard foam surfaces Very uncomfortable	Patient comfort assessed using a standardised question and a visual rating scale: very uncomfortable, uncomfortable, adequate, comfortable, very comfortable, no response obtained.

	Adequate 6/90 Comfortable 62/90 Very comfortable 11/90 No response 11/90 Comfortable or very comfortable 81.1%	0/80 Uncomfortable 2/80 Adequate 44/80 Comfortable 26/80 Very comfortable 0/80 No response 8/80 Comfortable or very comfortable 32.5%	
Gray 2000	• Transfoamwave Very uncomfortable 0/47 Uncomfortable 0/47 Adequate 3/47 Comfortable 26/47 Very comfortable 18/47	• Transfoam Very uncomfortable 0/48 Uncomfortable 1/48 Adequate 2/48 Comfortable 34/48 Very comfortable 11/48	Comfort ratings, on a 5-point scale from 'very uncomfortable' to 'very comfortable'.
Whittingham 1999	Data not presented	Data not presented	Comfort ratings similar for all 6 mattresses initially; however this altered by the end of the 12 months.

Figure 1

Study flow diagram


1624 records identified through electronic searches (including 1164 from electronic databases and 460 from trial registries)
6 additional records identified through other sources (including scanning the reference lists of 14 relevant systematic reviews identified in database searches; tracing relevant trial registry records)
1412 records after duplicates removed
1412 records screened
1178 records excluded
(1) 142 studies with 177 full-text articles excluded, with reasons
Irrelevant and ineligible interventions (e.g. other beds or mattresses, heel suspending devices, cushions; 55 studies)
Ineligible study design (e.g. non-RCT, reviews, commentary articles; 52 studies)
Studies focused on the treatment rather than prevention of pressure ulcers (20 studies)
Incorrect randomisation and non-randomised methods (eight studies)
Studies with ineligible outcomes (e.g. the breakdown of flaps after operations, interface pressure; four studies)
Clinical trials that were withdrawn (two studies)
Ineligible participants (healthy subjects; one study)

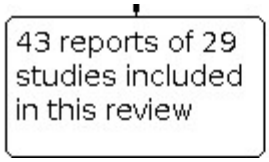


Figure 2

Risk of bias summary: review authors' judgements about each risk of bias item for each included study

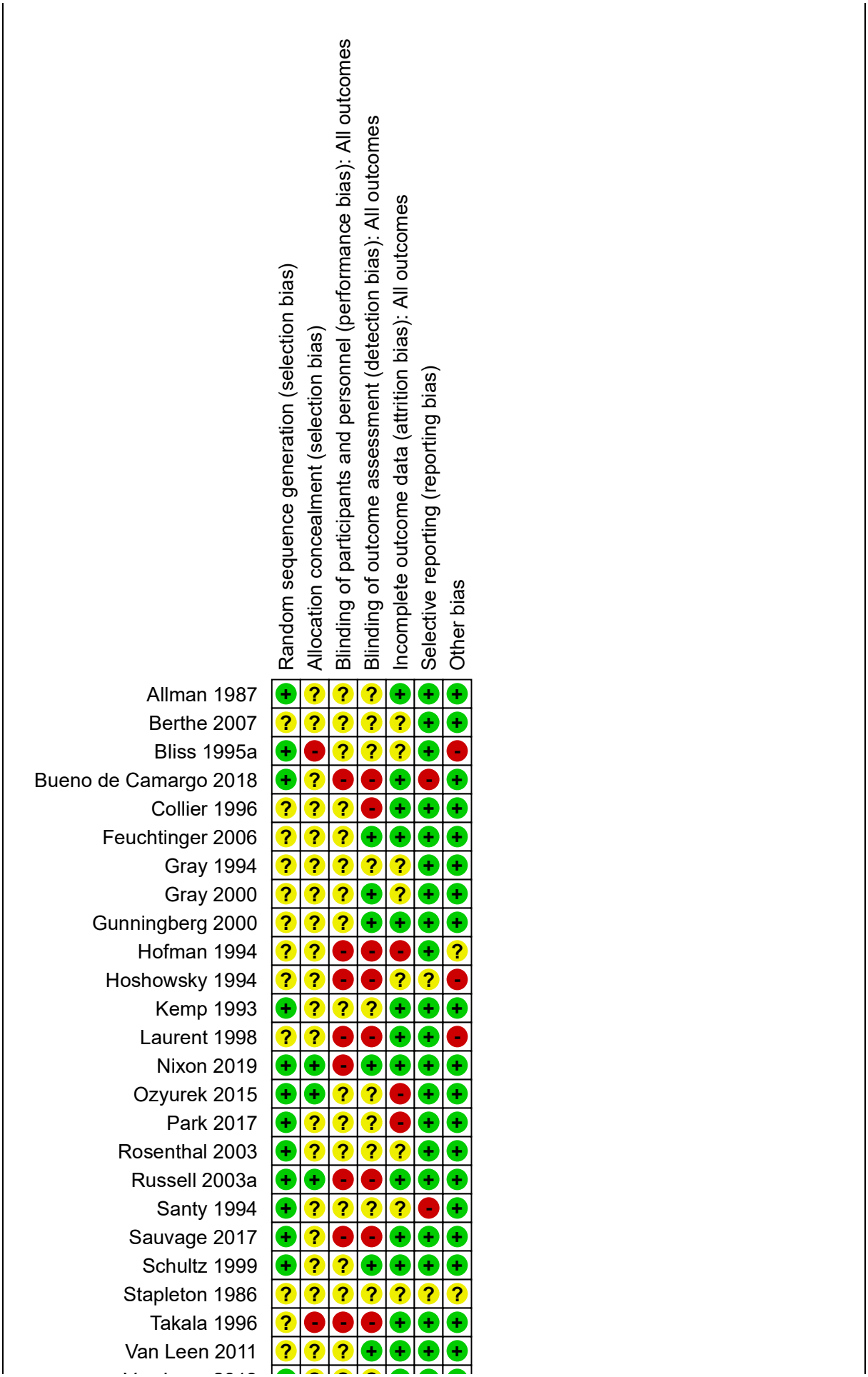
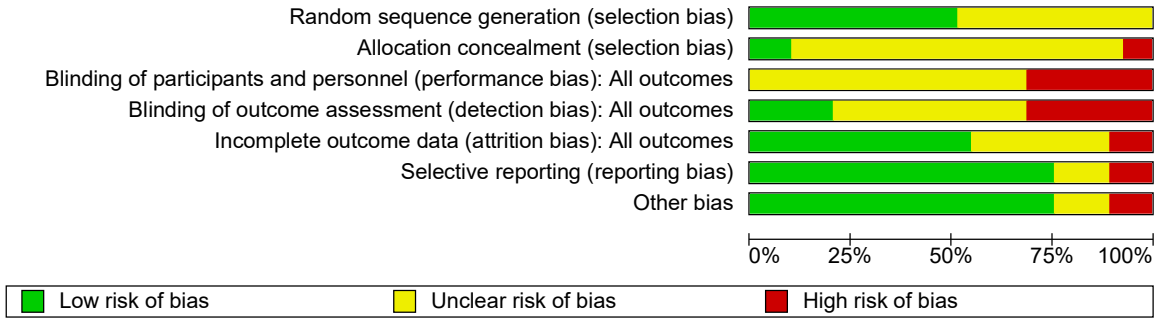

Random sequence generation (selection bias)
Allocation concealment (selection bias)
Blinding of participants and personnel (performance bias): All outcomes
Blinding of outcome assessment (detection bias): All outcomes
Incomplete outcome data (attrition bias): All outcomes
Selective reporting (reporting bias)
Other bias
Allman 1987
Berthe 2007
Bliss 1995a
Bueno de Camargo 2018
Collier 1996
Feuchtinger 2006
Gray 1994
Gray 2000
Gunningberg 2000
Hofman 1994
Hoshowsky 1994
Kemp 1993
Laurent 1998
Nixon 2019
Ozyurek 2015
Park 2017
Rosenthal 2003
Russell 2003a
Santy 1994
Sauvage 2017
Schultz 1999
Stapleton 1986
Takala 1996
Van Leen 2011

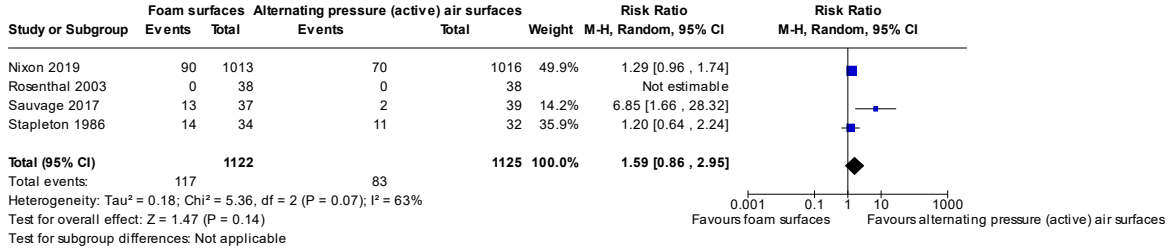
Figure 3

Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



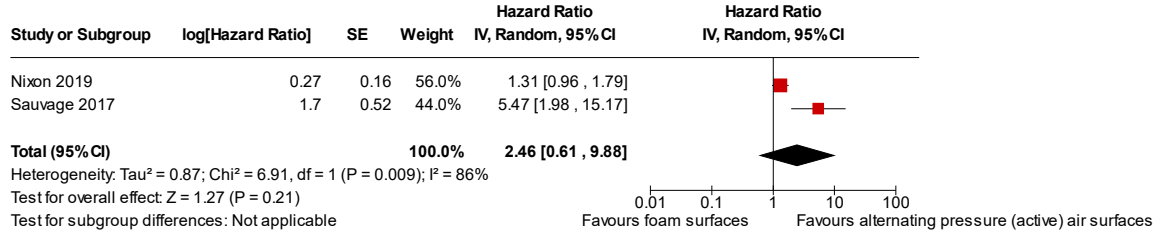
Analysis 1.1

Comparison 1: Foam surfaces compared with alternating pressure (active) air surfaces, Outcome 1: Proportion of participants developing a new pressure ulcer



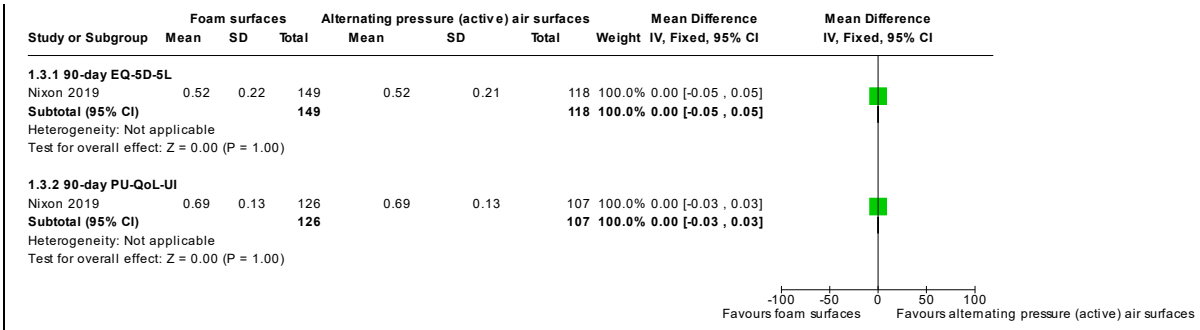
Analysis 1.2

Comparison 1: Foam surfaces compared with alternating pressure (active) air surfaces, Outcome 2: Time-to-pressure ulcer incidence



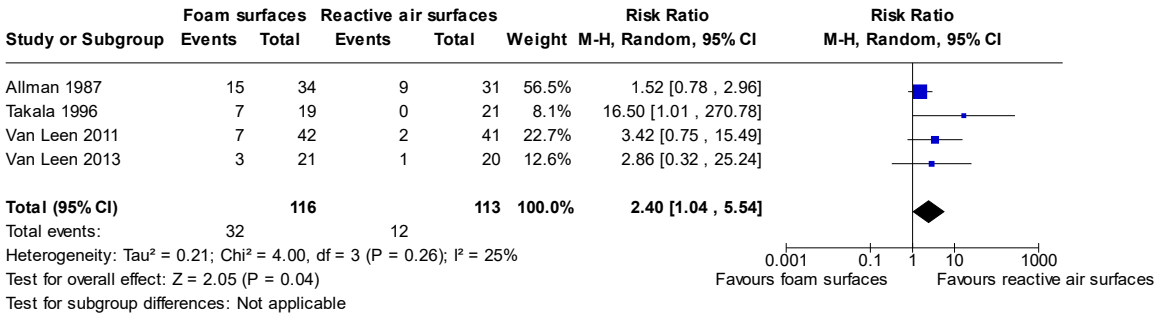
Analysis 1.3

Comparison 1: Foam surfaces compared with alternating pressure (active) air surfaces, Outcome 3: Health-related quality of life



Analysis 2.1

Comparison 2: Foam surfaces compared with reactive air surfaces, Outcome 1: Proportion of participants developing a new pressure ulcer



Analysis 3.1

Comparison 3: Foam surfaces compared with reactive fibre surfaces, Outcome 1: Proportion of participants developing a new pressure ulcer